RESEARCH ARTICLE

Toward a comprehensive framework for nanomaterials: An interdisciplinary assessment of the current Environmental Health and Safety Regulation regarding the handling of carbon nanotubes

The United States has recently paid significant attention to potential environmental health and safety concerns surrounding nanomaterials. Still, there exist several policy barriers to constructing effective regulation. These policy barriers include *public awareness and perception, an inadequate classification system, a deficient assessment process*, and *industry cooperation*. While public perception and industry cooperation vary greatly by country and trade, our team finds that a critical failure in the assessment and classification processes is the insufficient testing framework for classifying environmental health and safety (EHS) risk. In large part, this is due to relative novelty of the field but is also a result of the wide variety of new and under researched variables relevant to the unique health risks posed by nanomaterials. One area we believe deserves more attention in the Environmental Protection Agency's (EPA) current approach for assessing the potential toxicity of airborne nanomaterials, specifically in regards to issues of agglomeration. To better understand the potential EHS risk associated with airborne agglomeration of nanoparticles, we examine carbon nanotubes (CNTs) a nanomaterial touted for use in several consumer technologies. The first section of this paper provides a summary of the recent approaches to EHS regulation of nanomaterials. In this section we target four main policy barriers that are hindering effective EHS regulation for the research sectors in the life cycle of nanomaterial development across several government agencies. The second section is a review of the toxicology literature on inhalation risk associated with CNTs. The third section outlines the series of aerosols tests we conducted to characterize common exposure mechanisms in terms of airborne nanotubes and to determine whether current exposure levels of carbon nanotubes are acceptable under existing industry regulation. We measure exposure levels in terms of number concentration ($\#/cm^3$) and mass concentration (mg/m^3) for vertically aligned CNTs and dispersed single and multi-walled CNTs. We conclude that CNTs may pose an inhalation risk to people in a manufacturing or laboratory setting and that new OSHA exposure levels need to be set for nanomaterials to secure a safe working environment. Additionally, we believe that NIOSH needs to invest in CNT aerosol studies to better develop thorough chemical and physical test processes, understand the inhalation risks associated with nanomaterials, and build toward comprehensive framework for assessment and classification of EHS risks.

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BACKGROUND ON NANOMATERIALS

The European Union has defined a nanomaterial as "A natural, incidental or manufactured material containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50% or more of the particles in the number size distribution, one or more external dimensions is in the size range 1–100 nm."[1] While the US does not yet have a legal definition, the National Nanotechnology Initiative (NNI) recognizes a similar definition without a specified 50% cut-point.[2] Nanomaterials can be further sub-divided by the dimension of nanoscale confinement; materials with all three dimensions on the order of a nanometer are referred to as nanoparticles. Materials with two nanoscale dimensions are termed nanotubes or nanowires. These materials possess a much higher surface area to volume ratio than the bulk, such that the macroscopic properties are heavily influenced by the surface atoms which results in significantly different chemical and physical behavior.[3]

Nanomaterials began wide application in research and development in the mid-1990s when the focus on renewable energy technologies became a world-wide initiative. This simultaneous development was not by chance; due to their unique thermal, electrical and physical properties, nanomaterials have initiated a change in the world of science and engineering. Estimates by Lux Nanotechnology suggest that the global value of nanotechnology products sold in 2009 was approximately $254 billion;[4] however, given that the nanotechnology research has only been ongoing for the past 20 years, the potential for growth is enormous. Many of the applications in the market today use the nanomaterials passively, such as for coatings or incorporated into ceramics. Active nanostructures, such as Intel's tri-gate 3-D transistor, exploit the enhanced electrical properties of a nanomaterial.[5]

Given that nanomaterials are critical to the development of consumer technologies, it is necessary to understand the full implications of such reliance. Recently, there have been increasing calls from industrialized countries and emerging economies to examine the implications of a nano-enabled world. In particular, what are the possible human health or environmental impacts related to nanomaterials and how should these impacts be incorporated when conducting risk-assessment analysis and life cycle analysis? Unfortunately, the regulatory approaches to EHS of nanomaterials vary by industry, sector, application, country, and even state. Countries in Europe and Asia have initiated risk management frameworks for analyzing the physical and chemical transformations of nanomaterials, from initial research applications to end-user products. The United States has made significant efforts at researching the potential health impacts associated with nanomaterials, but has yet to develop a comprehensive framework for EHS assessment or federal regulation in regards to workplace exposure or safe handling. As a result, EHS regulation in the United States, particularly in regards to research and manufacturing, is often dictated by industry oversight. And while there do exist industry organizations concerned with the issues of nanotoxicology and the variant risk-management framework employed by different countries, these organizations are often motivated to reduce potential trade barriers, not insure the health of their researchers and manufacturers.

An overview of the recent national and industry approaches to Environmental Health & Safety Regulation of nanomaterials and the barriers to EHS Regulation in the United States

Over the past decade there has been a growing movement in many industrialized countries and emerging economies for EHS regulation of nanomaterials. The major theoretical advance in EHS assessment of nanomaterials has been the recognition that the material properties play a determination role in engineering nanomaterials conditioning, dissemination, exposure, and hazard generation at the nano-bio interface. As a result, many countries have recognized that since a large number of novel materials and material properties are continuously being introduced, it is imperative to develop a robust scientific platform to understand the relationship of these properties to EHS outcomes.[6] In general, current regulatory activities are still focused on reviewing whether, why, and when currently existing nanomaterials are hazardous, and whether and how humans or the environment are exposed to these hazards. Many countries have set up advisory boards or entire federal agencies dedicated to exploring these topics as well as their implications for risk assessment and life cycle analysis. A few countries have gone as far to introduce consumer labeling of end-user products containing nanomaterials. Many European countries have state-specific activities on regulation of nanomaterials mainly related to occupational safety and health aspects, chemicals, and foods. Of all of the EU member states, France, Germany, Switzerland, the Netherlands, and the UK have been the most aggressive in establishing specific requirements on manufacturers and importers of nanomaterials into its internal markets.[1] Outside of the EU,

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[1] OSHA aspects of nanomaterials, in general, focus on carbon nanotubes, medicinal products, medical devices.

Canada, the United States, Australia, and Taiwan are leading in the EHS regulatory push. In 2010, the US Congress appropriated an estimated $1.8 billion for nanotechnology R&D, nearly four times the $464 million appropriated for nanotechnology R&D in 2001. In fact, the United States leads all nations in known public investments in nanotechnology R&D. In addition the amount of funding intended explicitly for research on the environmental, health and safety aspects of nanotechnology has been increased from $37.7 M in 2006 to $123.5 M in 2012.[2]

In regards to EHS regulation of nanomaterials, the primary regulatory agency is the Environmental Protection Agency (EPA). Under the EPA's Toxic Substances Control Act (TSCA) there exists a branch dedicated to the regulation of nanomaterials. However, only recently has the EPA been able to identify and regulate nanomaterials. Originally, nanomaterials were not explicitly mentioned in the TSCA statute and there was no system for classification or risk assessment. For example, in 2007 the EPA classified nano forms of existing chemicals as existing rather than new chemicals, thereby removing the only means under the TSCA to review nanomaterials before entering the market.

More recently, a series of actions have been put in place to certify notification and registration of nanomaterials. On February 13, 2012 the EPA announced the availability of its *Fall 2011 Regulatory Agenda* regarding nanoscale materials. On the docket was a new a test rule and a significant new use rule (SNUR).[7] Significant new use rules require companies to notify the EPA in case of any significant new use of existing chemicals at least 90 days before activity. The SNUR has been issued for carbon nanotubes and other fullerenes. The SNUR also stated that the EPA is preparing a proposal requiring manufacturers of nanomaterials to inform the Agency on information related to production volume, manufacturing and processing methods, and available health and safety data. The new test rule requires manufacturers and processors, and importers of nanomaterials to conduct

testing for health effects, ecological effects, as well as provide material characterization data. The new test rule has been issued for carbon nanotubes, alumina, certain clays and spray-applied nanomaterials. The EPA is planning to adopt similar procedures on a regular basis for other nanomaterials, and is putting significant effort toward researching the use, characteristics and safety issues of individual nanomaterials before they are put on the market.

Another regulatory agency is the Occupational Safety and Health Administration (OSHA), which is charged with regulating safety and health legislation in the workplace. OSHA sets permissible exposure limits (PEL) for chemicals and other materials found in the workplace as well as employee access to information, requirements for the use of personal protective equipment, and requirements for safety procedures. Since OSHA already sets and enforces PELs for workplace safety, it would be the logical organization tasked with enforcing a limit for respirable exposure to nanomaterials. The current PEL for graphite is 5 mg/m^3 based on an 8 hour time weighted average (TWA). Respirable graphite typically has aerodynamic diameters on the order of μm or more, several orders of magnitude larger diameters that may be encountered in engineered nanomaterials.[8]

Regulatory efforts are supported by two major federal departments which exist primarily to further the development of the nanotechnology industry and assess the implications of the expanded commercialization of nanomaterials.[8] The National Nanotechnology Initiative (NNI) serves as the central point of communication and collaboration for the 25 Federal agencies engaged in nanotechnology research. In 2012 the Federal Budget allocated $2.1 billion for the NNI to aide in industry development. Within the NNI, the National Nanotechnology Coordination Office (NCO) coordinates NNI efforts and is primarily tasked with avoiding duplication. However, neither the NNI nor the NCO has any authority to delegate research or mandate research strategies in regards to EHS, life cycle assess-

ments, or risk analysis. The National Institute of Occupational Health and Safety (NIOSH), a subset of the Center for Disease Control, conducts research and provides guidance on the occupational safety and health implications and applications of nanotechnology and offers interim guidelines based on current scientific knowledge. Recently, NIOSH took on the responsibility of conducting research and developing guidance on the health and safety of workers using CNTs. Recognizing that workers generally have higher exposures to toxicants and hazardous agents and greater health risks from these exposures than the general population, NIOSH has produced guidelines and recommendations foe workplace safety to minimize potential health risks associated with exposure to CNT and CNF. However, until further research can fully elucidate the physicochemical properties of CNT and CNF that define their inhalation toxicity in handling CNTs, NIOSH guidelines are not federally mandated.[9]

Individual states may enforce their own legislation regulation of nanomaterials, as long as it does not conflict with federal law. For example, California, recently implemented a Chemical Information Call-In program for six nanomaterials: Nanocerium oxide, Nanosilver, Nanotitanium dioxide, Nanovalent iron, Nanozinc oxide, and Quantum dots.[10]

However, over the past few years there have been several attempts to produce a standardized best practices approach for the nanomaterial industry. For example, in 2005, NanoSafe was developed between small business, academia, and NIOSH. NanoSafe is a five-point program that encourages industry engagement on environmental safety issues in the nanotechnology workplace within five components: facility management, product stewardship, workforce protection, environmental management, and emerging technologies and strategies.[10] Today, several smaller nanomaterial firms use NanoSafe for addressing EHS concerns in manufacturing. Additionally, several university labs, including Delaware University, Florida State University, and University of California, have

implemented regulatory actions for their developmental research. And many industry associations, including the American Chemistry Council (ACC), have established councils and boards dedicated to advancing the understanding and impacts of the nanomaterial industry. Currently the ACC is working on substantiating a comprehensive definition for engineered nanomaterials so to better guide the regulatory process.[11]

While public funding for EHS studies has increased over the past years, the United States currently does not have any comprehensive legislation regarding EHS standards for nanomaterials for research and development or manufacturing, or any standard evaluation process in regards to life cycle analysis or risk assessment. This is due in part to the fact that the nanomaterial industry is fairly new and extremely ubiquitous, making regulation inherently cumbersome.[12] However, there exist additional policy barriers that have prevented the United States, as well as other countries, from constructing and implementing regulations. In this section we provide an overview of the major policy barriers and concerns facing the US federal regulatory process and the relevant regulatory structures for EHS standards. Additionally this section summarizes the attempts of other countries to overcome these barriers and the recommendations from recent literature on the subject matter. In our analysis of recent government and non-government reports on the EHS regulatory process, we have identified four major policy barriers facing EHS regulation of nanomaterials: *cooperation of private industry, public awareness, an inadequate classification system,* and *a deficient assessment process.*

Cooperation of private industry

A strong private–public partnership is important to the development of any commercial regulation but it is critical to understanding and constructing EHS regulation for nanomaterials. Without *private industry cooperation,* the EPA is severely handicapped in understanding the increasingly numerous factors relevant to the classification and assessment process.

Historically, in the United States, private industry has been reluctant to willingly share what is often proprietary information on manufacturing processes for the sake of potentially conflicting regulation.[13] In the United States, as well as in other industrialized counties, regulatory agencies have tried to engage with the nanotechnology industry, but private manufacturers are generally disinclined to share relevant information on manufacturing processes and design due to concerns about costs, trade secrets, and the concern over a of public release of confidential business information.[14] However, recent research shows that in regards to EHS standards for the research, manufacturing, and handling of nanomaterials, many industry representatives feel the need for government intervention. A survey of business leaders in the field of nanotechnology indicated that nearly two-thirds believe that "the risks to the public, the workforce, and the environment due to exposure to nano particles are 'not known,'" and 97% believe that it is very important or somewhat important for the government to address potential health effects and environmental risks that may be associated with nanotechnology.[15]

Public awareness and perception

While *public awareness* of nanotechnology and nanomaterials is increasing, the vast majority of Americans are still relatively unaware of nanomaterials' application and presence in their daily lives. In 2007, the Woodrow Wilson International Center for Scholars' Project on Emerging Nanotechnologies (PEN) conducted a nationwide poll of adults' attitudes and perceptions of nanotechnology. The study that found more than 42% had "heard nothing at all" about nanotechnology, while only 6% said they had "heard a lot."[16] Findings from the survey also indicated that majorities of Americans feel that the federal government (55%), universities and independent researchers (54%) all have a role in overseeing scientific and technological advancements such as nanotechnology as opposed to relying on self-regulation by private companies and industry.[17] More importantly, the study found

that, while the majority of Americans had no opinion on the risks versus the benefits of nanotechnology, those who did have an opinion were twice as likely to believe that the risks of nanomaterials far outweighed the benefits. The lack of public awareness provides both opportunities and challenges for policy makers involved in the EHS regulatory process.

On the one hand, a lack of public awareness provides policy makers with an opportunity to establish confidence in both the nanomaterial industry and the regulatory agencies charged with insuring public safety. In fact, many countries have developed publicly funded awareness programs, committed to educating the public on the risks and benefits of nanomaterials. In 2012, Thailand initiated the Nanosafety and Ethics Strategic Plan (2012–2016). The aim of the plan is to work in parallel with nanotechnology development to prevent and minimize potential risks related to nanomaterials. A primary strategy is the promotion of public engagement activities that promote public awareness of the direct and indirect effects of nanomaterials and nano-enabled products in regards to health and environment.[18]

On the other hand, a failure to properly educate the public could significantly impact the public perception of risk and create an unfounded hypersensitivity. Additionally, a reliance on public media to educate the public may also fail to adequately reach previously, uninformed constituents. Currently, the overall framing of nanotechnology and nanomaterials in media outlets is positive, but previous research has shown that cultural predispositions,[19] religious views,[20] and perceptions of scientific authority[19] shape how people translate media information into attitudes toward nanotechnology. As a result, values and predispositions can serve as perceptual filters,[20a] and the same piece of information will be interpreted differently depending on the audience's pre-existing values and predispositions. Additionally, recent analyses of nationally representative trend data conclude that there is a widening knowledge gap about nanotechnology between the most and least educated

groups in the US.[21] In short, as technology evolves and nanomaterials become more ubiquitous, highly educated respondents become more familiar with nanotechnology and its applications, but less educated groups are potentially becoming less informed about nanotechnology and its EHS implications.[22] This means that policy makers face a major policy barrier in finding a way to educate the masses while overcoming any inherent, biased predispositions.

Inadequate classification system

The fundamental difficulty in constructing EHS regulation of nanomaterials is the basic understanding of the physical and chemical properties of nanomaterials, and more specifically, how these properties shape the EPA's chemical classification process. Currently, there exist several questions: How is a nanomaterial identifiable as a separate substance from its base chemical for regulation purposes? What are the potential risks unique to nanomaterials? How does the risk change throughout the supply chain? Such uncertainties make it extremely difficult to classify nanomaterials or produce the EHS studies necessary for regulation.

As mentioned previously, the EPA has struggled to determine an appropriate classification system for nanomaterials as well as recommend any legislation or regulation. The primary challenge with classification is that the corresponding inorganic and organic base chemicals may not be directly relevant to their sister nanomaterials, since their physical and biological properties are often different and determined by a combination of size, structure, and functionalization engineered to achieve specific product performance. As a result, there is currently no standardized taxonomy and terminology for nanomaterials which describes all aspects of their physical and chemical characteristics, together with the establishment of standardized use categories.[23]

According to the EPA, a nanochemical is new for purposes of regulation only if it has a molecular identity not already listed on the TSCA inventory. Since the EPA does not consider molecule size or reactivity in determining if a chemical is a new substance, it is possible for nanoscale versions of existing chemicals to escape EPA regulation. In regards to quantity or weight, the listed substances or the threshold values in the regulations are in some cases classified so that nanomaterials will not be included.[24] Another challenge in the classification process, particularly in regards to EHS and toxicity assessments, is an understanding of the complex relationships between sources and the related exposure pathways to many potential receptors. Finally, individual nanomaterials are not classified or assigned to designated categories in regards to reactivity, degradability/fate and transport, and eco-toxicity vs. human toxicity. All of which are relevant to life cycle and risk assessments.[25] In large part, these classification barriers are a result of a failure to treat nanomaterials as a wholly different category for regulation and a continued attempt to assess nanomaterials in reference to the established physical and chemical classification system of their base chemicals.

Deficient assessment process

The byproduct of an inadequate classification system is an unstructured and incomplete assessment process, making it extremely difficult to address potential EHS impacts of nanomaterials on humans and the environment. Currently there is no established assessment process that combines life cycle assessments and risk assessments, and incorporates the numerous stakeholders and explicit trade-offs of the nanomaterial and nanotechnology field.[25]

The EPA's current risk assessment model is inadequate for conducting a comprehensive evaluation of nanomaterials. This is primarily a result of the inadequate assessment approach the EPA has taken to physical and chemical toxicology evaluation. Nanomaterials present a unique challenge as they require incorporating the scientific community's uncertainty in basic physical and chemical properties, which is much larger than the uncertainty for base materials. For example, very little is understood about the agglomeration behaviors of different sized nanoparticles and their potential inhalation risks. As a result, certain nanomaterials may not fit in to the same physical classification system as their base materials.[25] Another major issue is that current EPA models may not be able to adequately model the EHS implications of nanomaterials throughout their life cycle and within the different components of the supply chain. For example, the potential EHS risk of nanoparticle agglomeration may be very different at the R&D or manufacturing stage then in its end-user application, as researchers and manufacturers often handle unbound nanomaterials. Another assessment barrier is in the ability to sample risk exposure of nanomaterials in a lab or manufacturing setting. The current laboratory sampling method used by OSHA to monitor the PEL for carbon black and PM2.5 is OSHA analytical method OSHA ID-196. In this method air is drawn through a Low Ash Polyvinynl Chloride (LAPVC) filter at 2 L/min for up to 8 eight hours and then weighed with a microbalance to calculate a time weighted average mass concentration. This method has the advantage of being relatively simple and inexpensive, since the device requires only a filter and small pump. In addition, it is relatively compact so that it can easily be worn by a person in the work place without disrupting their normal activities. Current instruments to characterize the size, number, and surface area of particles are all large, heavy, and expensive, making current aerosol measurement technology inadequate for widespread enforcement of a PEL for nanomaterials based on any of these criteria. These assessment issues warrant a new framework that builds from a unique understanding of each nanomaterial as opposed to an appraisal based on base material qualities.

It is also important to note that given the relative novelty and rapid advancement of nanotechnology, the implications of classifications may hold more weight than EPA models currently account for. The recommended tools used by the EPA for uncertainty analysis may not be easily applied to nanomaterials, as there is significant variety throughout different industries.[25] For

example, little attention has been paid to the differences between manufactured nanomaterials, engineered, and non-engineered nanomaterials, and the associated scientific as well as legal challenges of separating or not separating these materials for regulatory purposes. Finally, a clear understanding of risk perceptions, which can depend on multiple factors, is essential to assessment efforts. As noted previously, public perception of the risks is important in the regulatory process, and these perceptions may differ depending on cultural and religious predispositions. Furthermore, each stage of the supply chain contains different stakeholders with different perceptions of risk and EHS impact; the perceived risk of a lab researcher developing nanomaterials may be very different then an end-product consumer. Any differences in the risk perception models for nanomaterial should be addressed in the assessment process.

In attempts to overcome the classification barriers and incorporate the multi criterion necessary for adequate assessment, including industry cooperation, several countries have recently pushed for more stakeholder integration of the regulatory process. A new assessment process in Australia focuses on separating classification for intentionally manufactured nanomaterials and non-engineered anthropogenic nanomaterials and calls for the input and analysis from the scientific community for the best means of classification.[26] In May of 2011, the European Commission held the Joint JRC Nano Event and 2nd ENPRA Stakeholders Workshop. The Joint JRC Nano event was created to assess the recent regulatory and scientific developments in the EHS fields for nanomaterials. The event pulled together multiple stakeholders, including participants, from industry, government, NGOs, and academia. Additionally, the European Food and Safety Authority published a draft guidance providing more specific risk assessment information regarding the use of nanotechnology in food.[27]

In 2007, the Woodrow Wilson Center for International Scholars conducted a study on *Nanotechnology and Life Cycle Assessment*. To aide in the categorization process and properly assess the life cycle impacts from nanomaterials, the Woodrow Wilson Center recommended creating protocols and practical methodologies for toxicological studies in regards to dispersive versus non-dispersive uses, particularly information on the corresponding elementary flow; conducting fate and transport studies; scaling studies of nanomaterial for size, surface area, and conductivity; and conducting studies on the mobility of releases of nanomaterials in the environment (air emissions, water release, waste, etc.) at each life cycle stage- in regards to reactivity, fate and transport, and interactions with other sources of environmental impacts.[25]

In an attempt to resolve the issues facing risk assessments, the National Research Council (NRC) constructed a unique risk assessment framework for the evaluation of manufactured nanomaterials. The framework built upon traditional risk assessment frameworks to incorporate multiple stakeholders, technical exposure and hazard analysis, and strengthened management at each phase. The framework explicitly asks the questions of what are the available options to reduce identifiable hazards or exposures and how can risk assessment be used to evaluate the merits of the various options. Similar to the Woodrow Wilson study, when focusing on hazard identifications and dose-response parameters, the NRC recommends further analysis of mobility studies at each stage of the life cycle process.[16]

Several of the analysis components presented in the NRC framework have been implemented in the EU REACH program. The EU REACH program is the European Community Regulation on chemicals and their safe use. It deals with the Registration, Evaluation, Authorization and Restriction of Chemical substances. Additionally, the NNI has set a goal of incorporating the stakeholder analysis recommended by the NRC into its EHS life cycle assessments as well as an increase of available information for managing potential risks from nanomaterials. However, while the NRC did attempt to integrate industry cooperation in to the assessment process, it did not attempt to integrate industry response to EHS hazard identification or risk management in its assessment process. Currently, no country or region has fully adopted such a multi-faceted, risk-assessment approach as the one presented by the NRC.[28]

An overview of the current policy landscape and barriers facing EHS regulation concludes that current regulatory systems face significant challenges in adjusting assessment processes to adequately characterize the potential EHS implications of the growing nanomaterial market. However, while policy barriers including a lack of public awareness, an inadequate classification system and assessment process, and a weak partnership with private industry, continue to muddle the process, there have been significant efforts in the United States and Europe to build a comprehensive and integrated framework for assessment and classification of nanomaterials for EHS regulation. In the US the focus is still largely on determining the appropriate evaluation frameworks and which new variables should be included in EHS assessment.

BUILDING A COMPREHENSIVE FRAMEWORK FOR ASSESSING THE POTENTIAL EHS RISK OF NANOMATERIALS FOR CARBON NANOTUBE EXPOSURE IN A LABORATORY SETTING

Building a comprehensive framework for classification and EHS risk assessment of nanomaterials begins with the understanding that nanomaterials are separate entities from their base chemicals and need to be treated and tested accordingly. With that understanding, regulators must explore both basic and complex questions in regards to physical and chemical behavior, as well as any other attributes that may impact issues of EHS. Only once these questions are answered can regulators develop a classification system based on observed likeness between different nanomaterials. However, it should not be expected that nanomaterials would be classified similarly to their base materials. In fact, it is very possible

that shared physical and chemical properties of different base materials will not translate to their sister nanomaterials. One area that has been largely neglected is the characterization of nanoparticle agglomeration behavior. However, airborne agglomeration has significant implications for potential inhalation risks, particularly in the research and manufacturing setting. In attempts to better characterize the potential inhalation risks associated with nanoparticle agglomeration, we chose to evaluate one of the most common nanomaterials found in consumer goods and research labs, carbon nanotubes.[29] While we recognize that all stages of the life cycle process are important, in regards to developing EHS standards, we feel that the sectors needing greatest attention are the R&D and manufacturing environments, primarily because these environments require direct exposure to nanomaterials. In order to thoroughly evaluate CNTs, we first analyzed the current known health effects surrounding carbon nanotubes in regards to inhalation risks. We then conducted an aerosol study of carbon nanotubes to simulate exposure similar to one that could be encountered in a laboratory or manufacturing setting to determine how likely they are to deposit in the human respiratory tract. We are interested in whether or not current OSHA particulate limit standards for EHS risk of nanomaterials are sufficient. The current OSHA particulate limit is based upon mass concentration. While mass based measurements are often considered more desirable due to ability to create gravimetric filter personal respirators for workplace safety,[30] we believe the health effects are more strongly tied to the number concentration.

CARBON NANOTUBES

One of the most common nanomaterials used today is the carbon nanotube (CNTs), which have been a common research material since their discovery in 1991.[31] CNTs are a sub class of fullerene that are comprised of carbon atoms wrapped in a cylinder with a diameter of approximately one to three nanometers for single walled carbon nanotubes (SWCNTs). Multiwall carbon nanotubes (MWCNTs) consist of concentric cylinders of nanotubes with an overall diameter of approximately 30 nm.[32] They are chemical stabile and exhibit extremely high mechanical strength and stiffness while being light-weight; they also are an excellent conductor of electricity and heat.[33] This impressive list of properties not only lends CNTs for use in the energy sector and other engineering fields, but also for a wide range of bio-applications. Since the mid-2000s, this unique material has been researched as a drug delivery tool and as a cancer treatment option among many other health applications.[34] CNTs are one of the only nanomaterials currently produced at a commercial scale, and global commercial CNT production reached approximately $700 million for 2010 corresponding to the synthesis of 2,500 metric tons of CNTs.[35] The CNT production industry is forecasted to expand to $1.1 billion by 2016, producing approximately 13,000 tons of CNTs.[35]

Some of the first health studies on carbon nanotubes were published in 2004.[36] Both animal and human testing have been conducted in vitro and in vivo over the last eight years to understand the health effects of single-wall CNTs and multi-walled CNTs from various forms of exposure including dermal, eye, ingestion, and inhalation. In addition, the effect of surface modification has recently entered research focus (e.g., metallic impurities, functional groups, dispersing agents).[37] As summarized by Zhu and Li,[37b] in vitro models present more simplicity, consistency of experimental conditions, and reproducibility of results as compared to animal studies. Cellular work can also better predict the effects of impurities and chemical modification of CNTs. As a result, extensive in vitro studies have been performed to understand the cytotoxicity of CNTs. Functionalization of CNTs developed as a method to well-disperse the CNTs in the medium to prevent aggregation and ensure reliable in vitro studies.

An acknowledged issue throughout the literature is the lack of a standardized test method in the effort of understanding the health effects of CNTs.[34,38] Varied sizes of carbon nanotubes, dosages introduced to either the cell or living organism and detection/analysis methods have been used. However, it has been generally noted through in vitro studies that the cytotoxicity of CNTs is strongly dependent on the characteristics of the CNTs: type of CNT, impurities present, geometry, aggregation and modification.[33,37b,38a,39] In vivo studies have also been published realizing that, although they are harder to characterize and identify than in vitro testing, these studies better represent the exposure and correlated health effects.

Based on results from human and animal studies, airborne nanoparticles can be inhaled and deposited in the respiratory tract and can enter the blood stream and translocate to other organs.[40] In industry, CNTs are most likely to be inhaled which has been translated in the intensive studies regarding toxicity from inhalation. Studies that focus on the effects of CNTs in the lung cavities can be organized into one of two types: intratracheal instillation studies and inhalation studies. Intratracheal installation studies analyze the response that the body has to direct introduction of CNT into the trachea, moving directly to the lower respiratory tract, whereas inhalation studies address the introduction of CNTs to the upper respiratory tract (nasal/oral cavities), moving through the entire respiratory system and entering the lungs. Inhalation studies of CNTs may provide more definitive information about their potential toxicity in humans.[41] Based on work with SWCNTs and MWCNTs in mice and rats, it is generally reported that inhalation of CNTs results in inflammation and granuloma formation in the lung and associated lymph nodes as well as pulmonary toxicology and suppression of immune function.[39d,42]

CNTs have been compared to asbestos due to their long, thin fiber shape which may be an important factor in the development of disease. CNTs have been shown to have similar inflammatory effects as asbestos fibers, which are known to cause mesothelioma. As reported by NIOSH, when

mice were exposed to more than 20 μg of nanotubes, the tubes migrated from the lungs to the tissues that surround them, known as the pleura. This activity is one of the signs of asbestosis, a disease caused by exposure to asbestos.[43]

Researchers at the University of Edinburgh found that high aspect ratio MWCNTs marked inflammatory reaction and the formation of granulomas when injected into the abdominal cavity of mice, similar to the reaction of asbestos fibers. This reaction was not noted with short asbestos fibers, nanoparticulate carbon black and small aspect ratio MWCNTs. These findings suggest that the inflammatory response seen in this study may be due to the long, thin shape of the fibers.[44] Similar mesothelial responses were reported by Takagi et al.[45] and Poland et al.[46] As discussed by NIOSH, additional studies are needed to determine if this inflammatory response would be persistent and result in tumors of the abdominal wall. Additionally, the potential for migration of MWCNT through the lungs to the mesothelium after inhalation requires investigation. Long-term studies are also needed to determine whether CNTs can cause cancer such as mesothelioma in laboratory animals, including exposures by typical routes in humans (i.e., inhalation, dermal penetration, and ingestion) and at doses that include those equivalent to potential workplace exposures.[40]

Realistic inhalation exposure of animals to CNTs is a common discussion throughout the literature. A team at NIOSH was able to recreate the inhalation of airborne nanoparticles by getting mice to inhale small drops of liquid in which multi-walled carbon nanotubes were suspended. The mice also developed pulmonary fibrosis depending on the dose of nanotube exposure, and after seven days, inflammation was much worse than that seen after 56 days. It is acknowledged that high concentrations are not realistic, but that this is good supporting evidence for precautions to be taken.[47]

These studies indicate the need for more data regarding the possible exposure of workers to CNTs. Two main studies have been performed by Maynard et al.[48] and Han et al.[49] Both reported relatively low short-term airborne mass concentrations of SWCNT prior to use of engineering control measures. The latter study noted that the concentration decreased below the detectable level after implementing controls. NIOSH concluded that workers could also be exposed to ground CNTs used in polymer composites and other matrices or during cutting, grinding, or polishing of these materials. Given that exposure to CNTs causes interstitial fibrosis and pulmonary inflammation, it is prudent to minimize worker exposure to airborne CNTs.[40] Johnson et al. found that engineered nanomaterials can become airborne when mixed in a solution by sonication, especially when nanomaterials are functionalized in water. This finding supports the NIOSH warning that laboratory workers may be at increased risk of exposure to engineering nanomaterials.[50]

Finally, at the current inhalation exposure OSHA PEL for graphite (5 mg/m^3), Shvedova et al. estimates that workers may be at risk of developing lung lesions if exposed to SWCNT over a period of 20 days. This is based on research regarding the current deposition and clearance of MWCNTs from the conducting airways of mice.[8] Pauluhn concludes that an limit of 0.05 mg MWCNTs/m^3 (time weighted average) is considered to be protective to prevent lung injury in the workplace environment.[42g] These studies show that no longer can permissible exposure limits be based on the type material; size of material must now also be considered as we enter the nanotechnology future.

As discussed and as evident in the presented research, CNT health studies, though not standardized, generally report need for precautionary actions, specifically regarding inhalation concerns. It is known that workers exposed to aerosols of some manufactured or incidental microscopic (fine) and nanoscale (ultrafine) particles report adverse lung effects.[40] CNTs are toxic upon reaching the lunges in sufficient quantity[38b] and have been shown to produce more damage to the lungs than carbon black or silica.[47] Toxicity of CNTs has been attributed to their geometric similarity and behavior to asbestos as well as carbon composition which leads to diminished resistance to pathogenic attacks,[51] but continued research is needed to determine the key physical and chemical characteristics of nanoparticles that determine their hazard potential.[40]

For our experimental work, we focused on the generation of aerosol particles from CNTs. The prime interest in the aerosol study of carbon nanotubes is to determine how likely they are to deposit in the human respiratory tract. Although the study of CNT aerosols is relatively new, the study of particle deposition in the lungs has been studied for years and is well understood. Several different deposition models have been developed including the ICRP model (International Commission on Radiological Protection), which is an empirically based model that predicts the deposition fraction in three respiratory regions as a function of particle diameter.[30] The model is divided into three sections; the head airways region includes the nose, mouth, pharynx, and larynx. Figure 1 shows the ICRP model for the three regions along with total deposition.

Particles larger than 1 μm typically deposit in the head airways region since large particles are easily deposited through settling or impaction. Many of the smallest particles between 1 and 10 nm are deposited in the tracheobronchial region while particles from 5 to 150 nm tend to deposit within the alveolar region. The portions of the respiratory tract in the head airways and tracheobronchial regions are covered in protective mucus, which catches the deposited particles and slowly moves them out of the body. Unfortunately, the lungs do not have such protection so while deposited particles may only remain in the throat for hours or days, of prime interest for respiratory health effects is the range of particles from 5 to 150 nm since they tend to penetrate into the alveolar region and can remain in the lungs for weeks or even months.[30]

Aerosol CNT studies are still a relatively new area of study with most of the work conducted in the last 10 years. There is also quite a bit of variation in the test methods and equipment
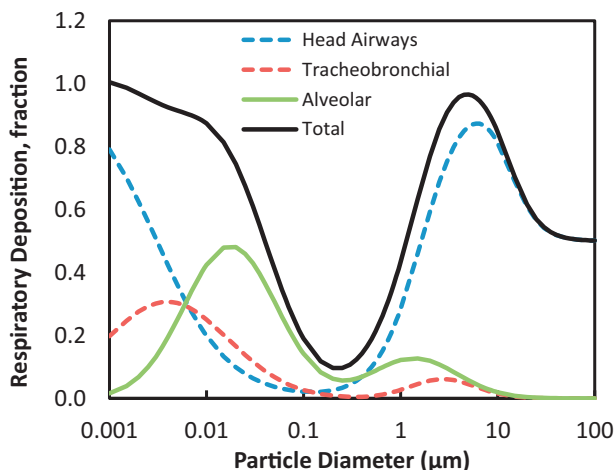
Figure 1. Particle deposition within the respiratory tract.

PARTICLE INSTRUMENTS

Four instruments were used to measure the CNT aerosols in terms of total number concentration, aerodynamic size distribution, mobility size distribution, and total mass concentration. The instruments employed were: the TSI Condensation Particle Counter (CPC), the Dekati Electrical Low Pressure Impactor (ELPI), Engine Exhaust Particle Sizer (EEPS), and the AVL Micro Soot Sensor (MSS). The CPC measures total number concentration between 3 and 1,000 nm. The ELPI and EEPS measure size distribution in the range of 10–10,000 nm and 6–530 nm, respectively. The MSS measures mass concentration of elemental carbon between 0.005 and 100 mg/m^3. The CPC and ELPI are used in several previous CNT aerosol studies,[54a,57] no literature was found using the EEPS or MSS. An FMPS was used by Bello et al., which is another TSI instrument similar to the EEPS.[55]

Materials

We chose to study SWCNT and MWCNT powders since these are the two most common materials used in CNT aerosol studies. While both materials are common in all three aforementioned scenarios MWCNTs are more common due to the fact they are easier and cheaper to produce.[30] The dispersed CNTs used in this study were purchased from MKnano; the MWCNTs (95% pure, diameter = 30–50 nm, length = 10–30 μm) are 15–50 times larger in diameter compared with the SWCNTs (90% pure, diameter = 1–2 nm, length = 5–30 μm). Excluding void space this means that the volume of a MWCNT is approximately 200 times greater than that of a SWCNT. These are similar to many previously studied CNTs in terms of geometry and composition.[52a,b,d–f]

In addition to using these common materials we chose to perform release mechanism tests on an additional material that is not commonly studied in the aerosol literature: vertically aligned CNT arrays (VACNTs). The VACNTs were synthesized on two four inch silicon wafers using the Black Magic Chemical Vapor Deposition system at Georgia Tech. The CNTs

used in the studies. The majority of the experiments focus on generating a steady distribution of airborne CNTs that can be measured for size distribution, number concentration, and or mass concentration.[52] Commonly single wall nanotubes (SWCNT) or multiwall carbon tubes (MWCNT) in dispersed powder form are used to generate an aerosol through various forms of agitation. Maynard et al. performed several experiments designed to quantify the true exposure encountered during laboratory handling of CNTs[48] and also developed a model to predict exposure.[53] The results from these studies varied depending on their purpose. Several were only attempting to report that they could produce a stable CNT aerosol for further studies,[52a,f] while several others attempted to quantify particle instrument response to CNTs.[54] Two studies attempted to measure the concentration levels in a manufacturing facility and one in a research facility under realistic operating conditions. Maynard et al. created a large (5′ × 6′ × 7′) sampling area enclosed with plastic at a manufacturing facility.[48] Bello et al. measured the ambient concentration levels in a manufacturing facility[55] and Han et al. measured the ambient levels in several research facilities.[49] Maynard et al. reported very low mass concentrations, below 53 μg/m^3, which are nearly 100 times below the OSHA PEL for graphite, and Han et al. reported concentrations up to

200 μg/m^3. Reported mean diameters varied from 10 nm to 10 μm, which is a wide range for a type of aerosol. For comparison, soot agglomerates from diesel engines are typically 10–100 nm in mean diameter,[56] which is a factor of ten rather than a factor of 1,000 as seen in the CNT studies. Typical number concentrations range from 10^2 to 10^6 #/cm^3; however the number concentration is expected to be highly dependent upon the generation conditions so it is not surprising that such a wide range would be reported. The highest number concentration reported for a work environment was 10^4 #/cm^3 in two studies.[48,55] The wide variability of results between tests makes it somewhat difficult to directly compare different studies, however as more work is performed it will be easier to understand what results can be expected under certain testing scenarios.

Aerosol test of carbon nanotubes

As a part of this work, an experimental study was conducted at the Southwest Research Institute Nanoparticle Lab to measure the airborne size distribution, number concentration, and mass concentration of various CNTs under different conditions. An attempt was made to measure steady size distributions and use new test methods in an attempt to simulate possible nanomaterial release mechanisms that may be encountered in a laboratory or manufacturing environment.

were grown for 8 min at 850 °C using acetylene as the process gas. Prior to growth, a tri-layer catalyst (30 nm Ti/10 nm Al/3 nm Fe) was deposited on the first wafer. The Al and Fe serve to promote CNT growth while the Ti layer supports adhesion to the Si substrate. The second wafer was prepared in exactly the same way, but without the Ti layer. This was done to purposely create a VACNT with weaker adhesion to the substrate.

Experimental set-up and test plan

The testing can be split into two main categories: size distribution and release mechanism. The goal of size distribution testing was to create a stable aerosol that can be measured over a period of time and averaged to get an accurate picture of the size distribution, number concentration, and mass concentration of the CNTs being studied. This is the common methodology employed by the majority of previous studies since it is easier to control and set up compared to a simulation of release in a lab or manufacturing environment.[49,52,54,57]

To measure a steady state size distribution a bottle was attached to a vortex shaker and filled with small stainless steel balls (diameter = 4.5 mm) and CNT powder. HEPA filtered (particle free) air is introduced into the bottle through the bottom and flows upwards through the CNTs carrying them out of the cap of the bottle as shown in Figure 2.

The vortex shaker is a Cole Parmer (Model WU-04726-01) capable of variable rotation up to 3,600 rpm. 150 steel balls were placed in the bottle along with 40–120 mg of CNT powder. The background particle concentrations measured were below 15 #/cm^3 for all cases and typically below 5 #/cm^3 which is several orders of magnitude lower than the generated aerosol concentrations. This method of aerosol generation is similar to that used by Maynard et al.[48] and Ku at al.[54a] A flow rate of 2 Lpm passes through bottle while the total instrument flow rate is approximately 12.4 Lpm. The additional 10.4 Lpm of air is provided as HEPA filtered dilution flow downstream of the shaker, which results in a nominal dilution ratio of 5.2.
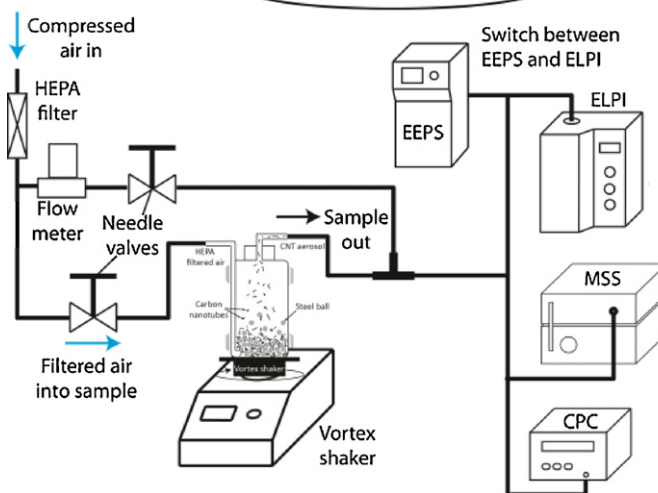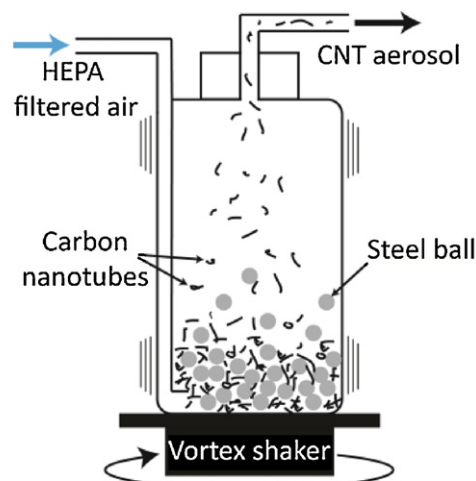

Figure 2. (a) Vortex shaker for CNT aerosol generation and (b) schematic of size distribution test setup.

When the shaker was turned on, a relatively stable aerosol was created that was measured for 3 min for each test to get an average measurement. Because the ELPI and EEPS require a high flow rate, it was not possible to measure simultaneously with both of these instruments without increasing the sample and dilution flows beyond acceptable levels. Instead, the two instruments were swapped in between each test so that the ELPI and EEPS measured every other test while the CPC and MSS measured every test and served as a comparison between the two. A schematic of the size distribution test setup can be viewed in Figure 2b. Although the number concentration varied somewhat from test to test, the size distributions measured by the EEPS and ELPI were relatively

repeatable indicating that it is reasonable to compare the average size distributions from the two instruments. It is believed that the variation in total number concentration was due primarily to the different amount of CNTs in the shaker bottle for each test, and this was considered acceptable as the goal of the experiment was to compare size distributions of the different CNTs. Comparing the aerodynamic and electric mobility diameter will also give information about the effective density of the materials.

The second portion of the study is release simulation testing, where the release of nanomaterial during handling is measured within a closed volume. Three methods of release that were chosen to test were agitation, fracture, and pour. A miniature glove
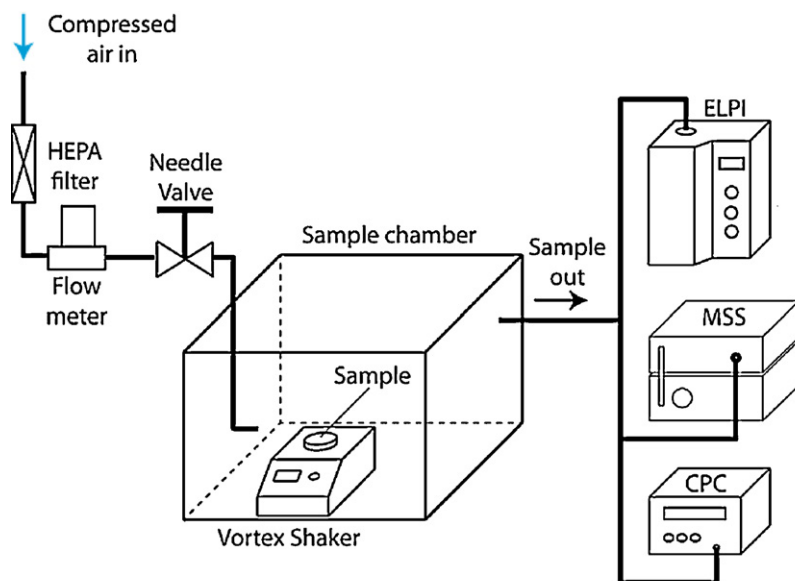
Figure 3. Experimental setup for handling and agitation tests.

the MWCNT and SWCNT. For each type of CNT three size distributions were measured using the EEPS and four were measured using the ELPI. The average EEPS size distributions for the MWCNT and SWCNT are shown in Figure 4.

Normalized concentrations are compared here, since differences in the concentration levels were caused by a number of factors in the generation system. The error bars on the data represent plus and minus one standard deviation based upon three repeat size distributions. It is clear that the majority of the size distribution is captured within the size range of the EEPS (5–560 nm). Some previous studies have reported size distributions in the micron size range for the aerodynamic diameter although the mobility diameter is typically slightly smaller[52a] [,e,54a]. The solid lines represent the best fit lognormal size distribution for the experimental data. The data fitting was performed using custom software that can fit either monomodal (single peak) or bimodal (dual peak) distributions with a mean diameter and geometric standard deviation (GSD). The MWCNT distribution is monomodal with a number mean diameter (NMD) of 62 nm and a GSD of 1.54. Based on the lognormal parameters for measured CNT size distributions, the SWCNT distribution is fit to a bimodal distribution with NMDs of 54 and 176 nm. .It is important to note that while the MWCNTs are six times larger than the SWCNTs in terms of an equivalent geometrical diameter, they
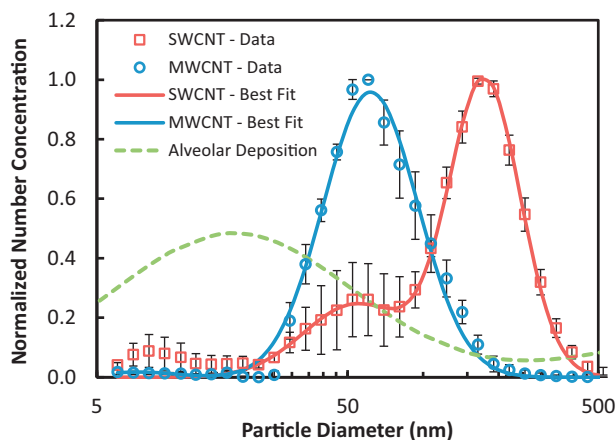
box was created using a 23 L rectangular box that was sealed except for an inlet port for clean air and an outlet port for the aerosol sample. Two sealed glove ports were made in the side of the sample chamber so that materials inside the box could be handled without breaking the seal. The CPC, ELPI, and MSS measured simultaneously from the outlet of the sample chamber with no additional dilution air. The setup can be seen in Figure 3.

The sample chamber was leak checked by its ability to hold a small positive pressure, and further verified by the low particle concentration achieved within the box (<10 #/cm^3) when the particle concentration in the lab was several orders of magnitude higher. When the vortex shaker was turned on inside the box without a sample no increase in the concentration was observed indicating that the equipment was not generating any measurable particles. The needle valve at the inlet of the chamber was used to adjust the flow meter to the correct total flow for all four instruments (21.4 Lpm). With a total box volume of 23 Liters, the residence time within the sample chamber is just over 1 min. The agitation tests were conducted by attaching a full VACNT wafer to the vortex shaker (which was sealed inside of the box). The rotational speed of the vortex shaker was gradually increased

until a release of particles was detected up to a maximum of 60 Hz. This was performed using both VACNT wafers. Fracture tests were performed using the VACNTs by taking tweezers and breaking pieces of the wafer off and measuring the resultant release of particles. The pour test was conducted by pouring several milligrams of MWCNT powder from a bag onto a piece of wax paper to simulate weighing CNT powder in an open environment.

RESULTS AND DISCUSSION

A total of 14 steady state size distributions were measured, seven for each

Figure 4. MWCNT and SWCNT EEPS size distributions.

appear to be approximately three times smaller than the SWCNTs in terms of the mobility diameter. This suggests that a number of SWCNTs are clumping together to form a single airborne particle, similar to what was observed by Maynard et al.[48] They showed that the SWCNTs tend to clump together in large aggregates, while Fujitani et al. observed MWCNTs collected both as individual tubes and agglomerates.[52a] Ku et al. measured the mean peak mobility diameter of SWCNTs to be between 20 and 60 nm depending on the generating conditions,[52d] which is much smaller than observed in this work. Maynard et al. observed a trimodal distribution for SWCNTs with peaks around 20, 200, and 2,000 nm.[48] Ku et al. used an electrospray generator, while Maynard et al. used a fluidized bed sieve shaker, and the present work used a vortex shaker; this indicates the airborne particle size of CNTs is likely to be heavily dependent upon the generation technique and experimental setup. The alveolar deposition curve is superimposed on the size distributions so that the inhalation risk of each size distribution can be better understood. The MWCNT particles reside within the range of high lung deposition, while the SWCNT particles are larger and pose less of an inhalation risk based upon the generation method used here.

As mentioned previously the EEPS measures the electrical mobility diameter while the ELPI measures the aerodynamic diameter. The two are related by the particle density; at 1 g/cm^3 the two diameters are equal, and with increased densities the aerodynamic diameter becomes larger.[30] The number mean diameters measured by the ELPI were similar to those found using the EEPS, but slightly larger. This is likely an indication that the density of the particles is greater than 1 g/cm^3, which is supported by previous findings.[52b] The most important result from the steady state testing is that each instrument supports the result that the SWCNT aerosol particles are larger than the MWCNT particles. A larger aerosol size for the smaller physical nanomaterial indicates that the inhalation risk of these materials cannot be understood by
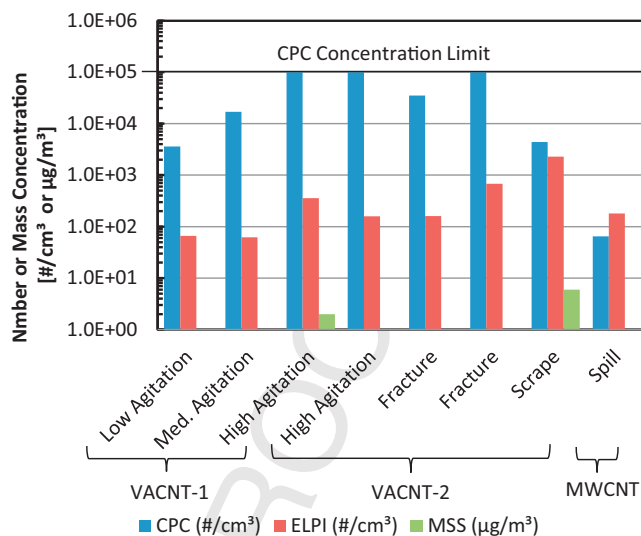

Figure 5. Peak concentrations encountered during handling experiments.

comparing their physical dimensions alone. A summary of the peak concentrations measured in each of the handling tests is shown in Figure 5. VACNT-1 refers to the wafer without the Ti adhesion layer, and VACNT-2 refers to the wafer with the Ti layer. MWCNT is the same dispersed CNTs used in the size distribution measurements.

Low, med., and high agitation refer to three positions on the dial of the vortex shaker at approximately 1/3, 2/3, and full speed respectively. Similar release rates were observed with both VACNT wafers indicating that the addition of a Ti adhesion layer had little influence on the aerosol generation behavior of the VACNT under agitation. The peak number concentration measured by the CPC goes above 10^5 #/cm^3 (maximum concentration limit) and is never greater than 2.3 × 10^5 #/cm^3 for the ELPI in the fracture and agitation tests. The fact that the ELPI measures several orders or magnitude lower than the CPC and the MSS does not detect any mass seems to indicate that the emitted particles are fairly small. The CPC has a lower detection limit of 3 nm, while the lower detection limit of the ELPI is approximately 25 nm; it is quite possible that a number of the airborne particles were between 3 and 25 nm. A portion of the discrepancy could also be due to the different measurement principles of the two instruments. Even

in the size distribution testing the ELPI and EEPS measured consistently lower than the CPC. The ELPI and EEPS both charge the particles and measure the resulting current, which relies upon accurately predicting the number of charges per particle. Recent studies have shown that the number of uncharged particles in a CNT aerosol is significantly different than that of spherical particles.[54a] This could have a substantial impact on the accuracy of the number concentration predicted by measurement techniques relying on particle charging and needs further investigation. It is interesting to note that the ELPI reported number concentration is on the same order as that of the CPC for the scrape and spill test likely indicating that these tests created larger aerosol particles through agglomeration. This is an indication that the aerosol generated from the same CNTs may be different depending upon handling mechanism (or aerosol generation technique). While particle concentrations exceeding 10^5 #/cm^3 may seem high, it is important to bear in mind that this concentration is based upon a 23 L sample chamber, and that the concentrations encountered in a full size room would be much smaller for the same emission rate (~5 × 10^9 #/min). The size of the glove box was chosen to provide enough room for sample handling while keeping the residence time short.

While this is not an entirely accurate characterization of the aerosol levels that may be encountered by those working in research or manufacturing facilities, it is intended to provide an idea of the emission rates that may be encountered during handling of CNTs. The high agitation is the maximum speed of the shaker, 60 Hz. Although this may seem like a high agitation frequency, it is not unlikely that certain AC motors or pumps could cause significant vibration at this frequency. The number of CNTs released during transient testing was not extremely high when considered in the context of larger workspaces, but it is important that CNTs attached to a substrate could still easily become airborne under the right conditions.

Conclusions and recommendations

From our assessment of the current US regulatory framework for EHS regulation of nanomaterials, we believe that while the regulatory agencies in place are adequate for constructing effective regulation, there is still significant work that needs to be done in order to construct effective EHS regulation on CNTs, particularly in respect to the incorporation and standardization of a wide range of variables unique to the assessment of nanomaterials. One area that we believe deserves further attention is the risk associated with airborne agglomeration. As such we provide two main recommendations for the existing regulatory bodies concerned with nanomaterials:

First, the NNI should invest in aerosol CNT research to develop a larger body of data for developing standards and to better understand and improve the measurement techniques and aerosol generation methods. Increasing the efforts of CNT aerosol research in the short term should help the EPA create sampling standards by which universities, private industry, and government agencies could directly compare results from different nanomaterials and develop more comprehensive analysis which could help influence future regulation. This process could begin immediately with an increase in funding for nanomaterials aerosol research.

Second, past aerosol studies along with our experimental research suggest

that OSHA should reassess its current exposure limit of carbon aerosols and consider a separate category for carbon nanostructured materials such as buckminsterfullerene and nanotubes. We recommend that NIOSH invest in further aerosol testing and that a permissible exposure limit needs to be explored based upon the number concentration of airborne nanomaterials in labs and manufacturing facilities. The current mass based particle standard is insufficient to protect against CNT inhalation hazards. With the support of research and recommendations from NIOSH, we believe that OSHA should also pursue similar aerosol testing for other nanomaterials. In conjunction with the implementation of a new number based PEL, a new standardized number concentration sampling method needs to be developed in order to facilitate straightforward and relatively inexpensive compliance with the standard. However, implementing a new standard will require new portable aerosol measurement devices, in order to monitor and enforce a new PEL measurement. As such, OSHA should work with the NNI to invest in the development of portable, inexpensive devices.

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