

The Factory of Tomorrow

How advances in material science and manufacturing technology are shaping the factory of tomorrow and the challenge to the Industrial Hygienist

Yuma Pacific-Southwest Section 40th Annual Meeting January 22, 2015

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Objectives

Understanding Two Key National Initiatives

- Nanotechnology
 - An overview of the key components of nanomaterial science
 - Benefits and concerns
 - Overview key EHS issues
 - Current state of knowledge
 - Summarize the risk management approaches being used today









Objectives

Understanding Two Key National Initiatives

- Advanced Manufacturing
 - What is 'Advanced Manufacturing'
 - Key drivers
 - Benefits and concerns
 - OS&H issues?
 - Current state of adoption
 - How will it change the workplace?







Nanotechnology









Economic Priority for the US



A Strategy for American Innovation: Driving Towards Sustainable Growth and Quality Jobs

"History should be our guide. The United States led the world's economies in the 20th century because we led the world in innovation. Today, the competition is keener; the challenge is tougher; and that is why innovation is more important than ever. It is the key to good, new jobs for the 21st century. That's how we will ensure a high quality of life for this generation and future generations. With these investments, we're planting the seeds of progress for our country, and good-paying, private-sector jobs for the American people."

-PRESIDENT BARACK OBAMA, AUGUST 5, 2009

The Administration is committed to strengthening and focusing investments in our world-class nanotechnology research and development pipeline; targeting support for nanotechnology transfer and facilitating commercial start-ups; and cross-disciplinary training and education of scientists and engineers in the new-generation workforce.

This will enable us to capitalize on our investments and stay at the cutting edge of this rapidly growing technology.







What is the US Investment?

The cumulative investment of NNI agencies since fiscal year 2001, including the 2015 request of \$1.5 Billion, now totals almost \$21 Billion.

Is EHS important?

Cumulative investments in nanotechnology-related environmental, health, and safety research since 2005 now total nearly \$900 million.









EHS is 'crucial' to commercialization...

Key Findings of the Review of NNI

- The US is the world leader in nanotechnology R&D and commercialization, but its lead may be transient
- The NNI has had catalytic and substantial impact on the field of nanotechnology
- The program management of NNI is effective but opportunities for improvement exist
- Economic competition from other countries has dramatically increased
- · Commercial activities have gained momentum as the field has evolved
- The scarcity of standardized commercialization data challenges the tracking of benefits of nanotechnology
- The identification and management of risks for environment, health and safety are crucial to the responsible commercialization of nanotechnologyrelated products
 - The lack of an American skilled workforce presents a significant challenge to the nanotechnology-related business community.

President's Council of Advisors for Science and Technology







Easy summary of current state

- Congress: Where are the new products and jobs?
- Industry: Innovation and commercialization must come closer
- EHS: We have some knowledge but a lot of unknowns

Challenge: move nanotechnology to market quickly and safely







Nanotechnology

- It is a priority: got it.
- What is it and how will it affect me as an Industrial Hygienist?
- Nanotechnlology is a huge collection of scientific disciplines. We will focus on the materials.
- Focus: <u>Nanomaterials</u> that are created by nanoscale science and engineering





Nanotechnology is Everywhere

- Not a matter of 'if', but of 'when'
- It is the new material science
- Boundaries between materials have been erased to exploit new activity
- Moving into the manufacturing workplace as 'new and improved' products are created
- Moving into established and advanced manufacturing processes.



Nanotechnology: A Review





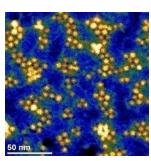


Nanoparticles: Some Old, Some New





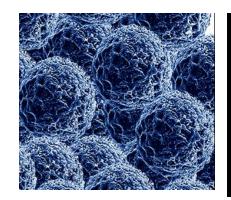


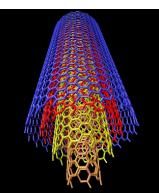












Naturally occurring

Man-made by-product

Engineered Nanomaterials (ENM)



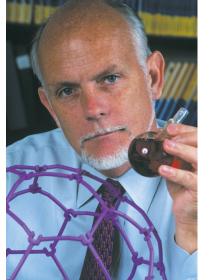






Nanotechnology: The Fast Definition

- Manipulating matter at the atomic level
- Creating materials that have new and unique properties because of their size.
- Creating structure and function at nanoscale



Richard Smalley

Nobel Prize Winner, Chemistry (1996)

Nanotechnology:

"The art and science of building stuff that does stuff at the nanometer scale"

AKA: Material science, one molecule at a time. (1943 - 2005)

"Just about anything can be made faster, stronger, smarter, smaller, better, etc., using nanomaterial science"







A 'Flat Earth' View of the Elements

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U	Вe											8	С	N	0	F	Ne
Na	Mg			_								Al	Si	P	s	CI	Α
ĸ	Ca	Sc	n	٧	Cr	Mn	Fe	Co	141	Cu	Zn	Ga	Ge	As	Se	Br	Kı
Rb	St	Y	23	Nb	Mo	Tc	Ru	Rh	Pd	Ag	Cd	In	Sn	Sb	Te	1	Xe
Cs	Ва		Hf	Ta	w	Re	Os	lir.	Pt	Au	Hg	π	Pb	Bi	Po	At	Rn
Fr	Ra																

La	Ce	Pr	Nd	Pm	Sm	Eu	Gd	Tb	Dy	Ho	Er	Tm	Yb	Lu
Ac	Th	Pa	U	Np	Pu	Am	Cm	Bk	Ct	Es	Fm	Md	No	Lr

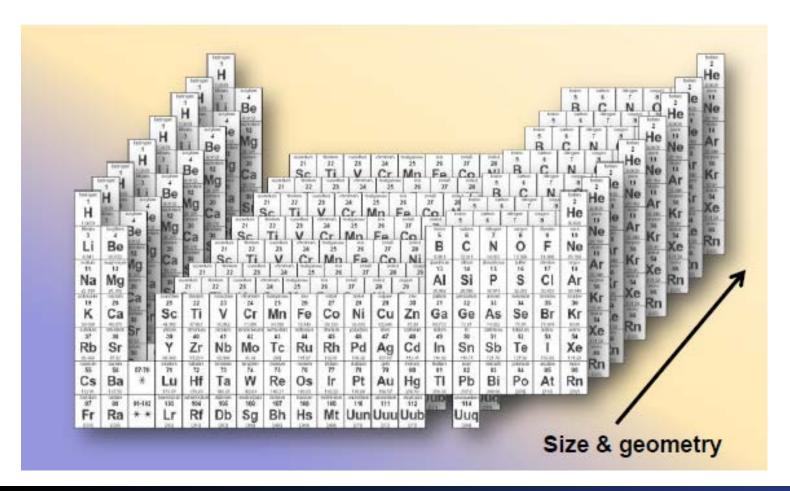








Nanomaterial Science: Opening the 3rd Dimension of the Periodic Table





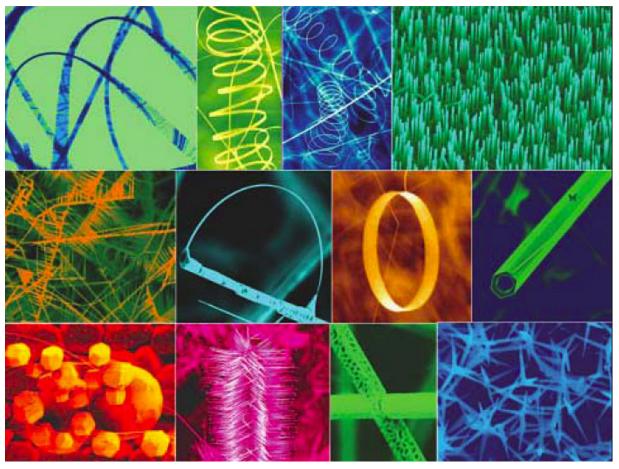






Zinc oxide nanoparticles

Same composition: different shapes and different chemical and biological activities



Source: Materials Today June 2004. Zhong Lin Wang, Georgia Institute of Technology



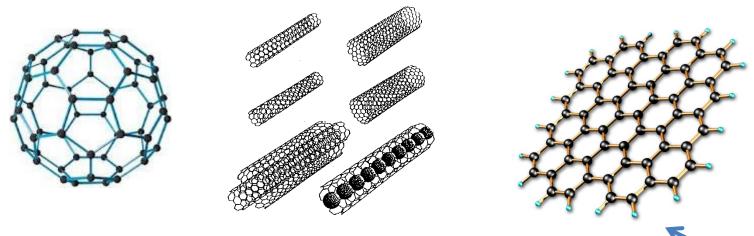








Your Grandfather's Carbon



The Nanomaterial designer's carbon

Built in the nm range

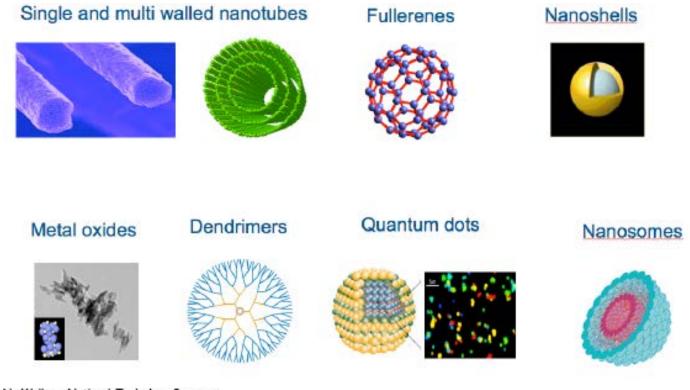








Nanoparticles: Many shapes, many chemistries



N. Walker, National Toxicology Program

Not all nanoparticles are the same





Nanotechnology: 30 Second Review

Old: Material behavior driven by chemistry and making things from big pieces

Nanoscale Science: making materials one molecule at a time at the nano scale

New: Material behavior driven by size, shape, surface chemistry. More active and efficient

Result: New material properties and behavior:

Higher or newer hazard?





Challenges of Nanotechnology for the Industrial Hygienist





Challenges of Nanotechnology

- Few 'new-to-the-world' materials, but many new forms of familiar materials
- Beneficial properties associated with the technology and the materials – highly promoted
- Potential hazards have been identified
- Action needed in an environment of uncertainty
- Potential for many 'generations' of the technology and the materials
- Moving into every sector





Applications of nanotechnology

Agriculture	More efficient, targeted delivery of plant nutrients, pesticides
Aerospace and Automotive	Lighter, stronger, self-healing materials
Medical	Targeted therapeutics, enhanced detection, new structural materials
Energy	More efficient fuel cells, solar collectors, transmission, storage
Environmental	New pollution control and remediation tools, sensors
Food	New safety sensors, food preservatives, nutrient additives, packaging
Materials	Self-cleaning glass, stain resistance, stronger materials, body armor
Water	New purification approaches, wastewater treatment









NANOTECHNOLOGY: In the Balance

THE PROMISE!

and

THE CONCERN?

Multiple Applications/Benefits

- Structural Engineering
- Electronics, Optics
- Food and Feed Industry
- Consumer Products
- Alternative Energy
- Soil/Water Remediation
- Nanomedicine:
 - therapeutic
 - diagnostic
 - drug delivery
 - cancer
 - nanosensors
 - nanorobotics

Consumer Fears/Perceived Risks

- Safety: Potential adverse effects
- Environmental Contamination
- Inadvertent Exposure (inhalation, dermal, ingestion)
- Susceptible Subpopulation
- Societal Implications
- Nanotoxicology:

 Safety Assessment of
 engineered Nanomaterials
 and of Nanotechnology
 enabled Applications

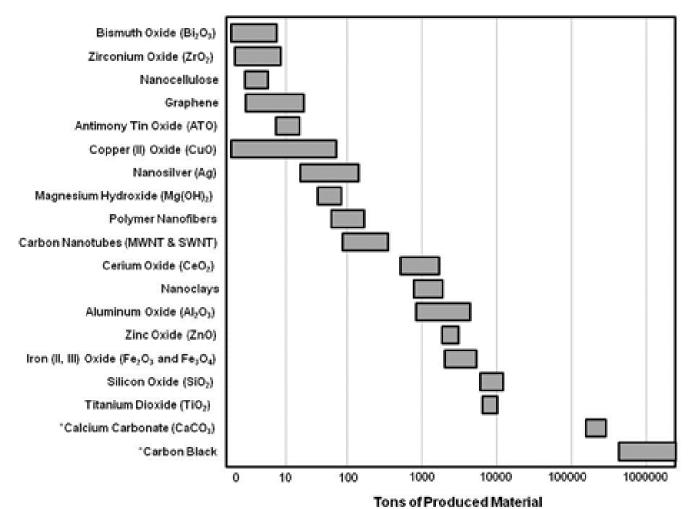








Commonly Produced and Used NM



Draft NIOSH Contract Report (C. Sayes, 2014)





National Cancer Institute

U.S. National Instit



Developing Small Tools with a Big Impact on Cancer

Search

Learn About Nanotechnology

Collaborate

Alliance in Action



News Spotlight

NEW ROUND OF ALLIANCE FUNDING WITH APPLICATION SUBMISSIONS DUE FALL 2014!

Application announcements for NCI's Cancer Nanotechnology Program are now published. Opening dates for the CCNEs (U54) and IRCNs (U01) are listed below with initial

Understanding the Potential



News &

ANNUAL

The Natior Alliance for Cancer puthe annua outlines the Alliance recommunit numerous articles, a communit advancing nanotechricalliance for Cancel Ca

Read the I

REQUEST SUMMARY

of Cancer









Home > Science & Research > Science and Research Special Topics > Nanotechnology

Science and Research Special Topics

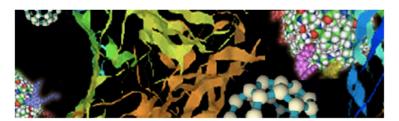
▶ Nanotechnology

Current Nanotechnology Programs at FDA

Resources for You

FDA Publications

Nanotechnology



The U.S. Food and Drug Administration (FDA) regulates a wide range of products, including foods, cosmetics, drugs, devices, veterinary products, and tobacco products some of which may utilize nanotechnology or contain nanomaterials. Nanotechnology allows scientists to create, explore, and manipulate materials measured in nanometers (billionths of a meter). Such materials can have chemical, physical, and biological properties that differ from those of their larger counterparts.

Spotlight

- FDA's Approach to Regulation of Nanotechnology Products
- 2013 Nanotechnology Regulatory Science Research Plan

Related Links

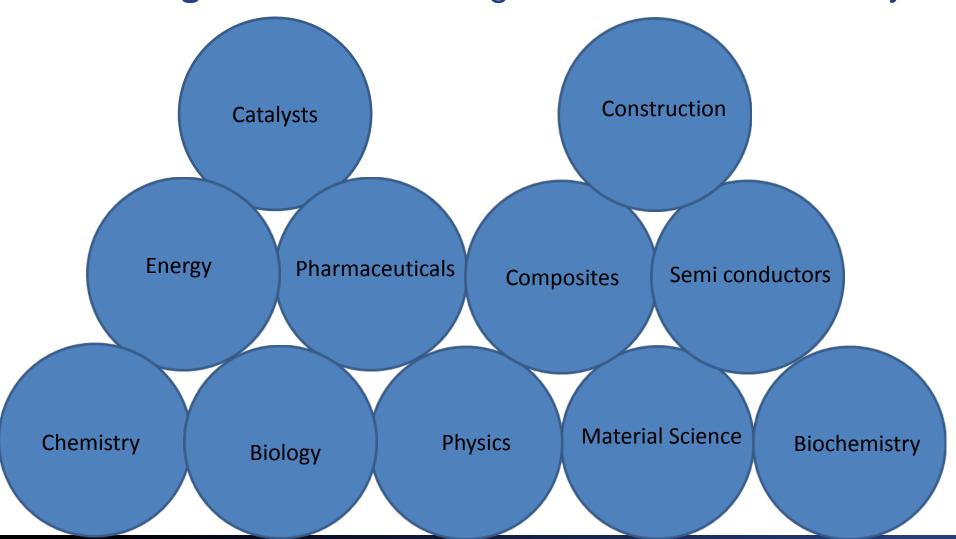
- · National Activities
- International Activities
- Nanotechnology Partnerships







Challenge: There is no single nanomaterial industry

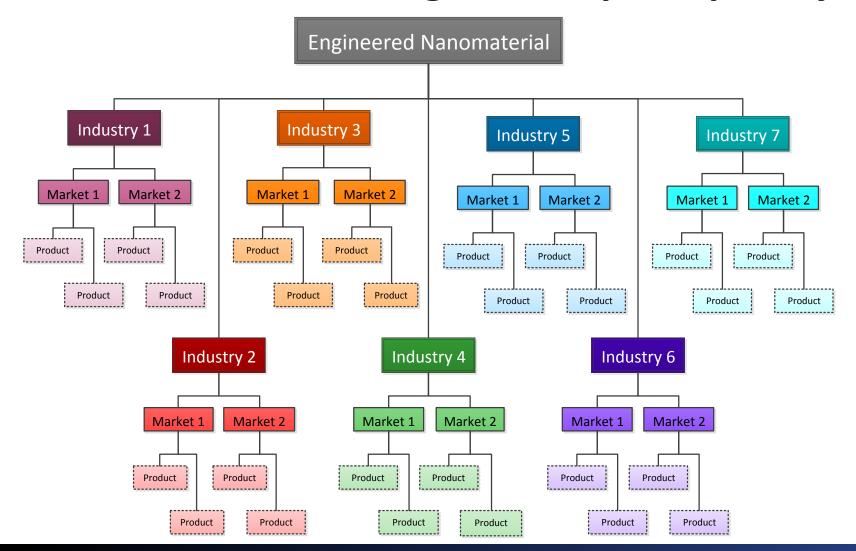








The ENM value chain gets complex quickly









Example consumer products that contain nanomaterials

www.nanotechproject.org/cpi/products

260 Den Nano Silver Far Infrared Anti-odor Healthy Socks

Company: TSUNG-HAU Technology

Category: Health and Fitness > Clothing

Origin: Taiwan

Nanomaterial: Silver

2C Auto Sealant PRO

Company: Nanosafeguard

Category: Automotive > Maintenance & Accessories

Origin: USA

Nanomaterial: Silicon dioxide

How much we know: Category 4 (Unsupported claim)

ASTOCIATE guard

K An Her Austra No

Cagari Ci

Workers: Make NM, formulate products

Consumers: use products

Public: Possible releases

Environment: Mfg emissions, waste,

weathering

928 Carbon/SL Record

Company: Bianchi

Category: Health and Fitness > Sporting Goods

Origin: Italy

Nanomaterial: Carbon



A La Mode Performance Long Sleeve Mock Neck

Company: Green Tee Apparel

Category: Health and Fitness > Clothing

Origin: USA

Nanomaterial: Polymer

How much we know: Category 4 (Unsupported claim)



AccuFlex® Evolution Golf Shaft

Category: Health and Fitness > Sporting Goods

Origin: USA

Nanomaterial: Carbon



Ace Casual White Paint

Company: Ace

Category: Home and Garden > Paint

Origin: USA

Nanomaterial: Titanium dioxide

How much we know: Category 5 (Not advertised by manufacturer)









Nanotechnology

Illustrates the challenges to society of a new technology

Beneficial properties Potential hazards
What to do when information is lacking or uncertain









NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH

NANOTECHNOLOGY
RESEARCH
CENTER

Reality !





It's not all clean rooms and electron microscopes



What Do We Know About Risk?

The Classic Risk Model

Hazard Identification

Is there reason to believe this could be harmful?

Exposure Assessment

Will there be exposure in real-world conditions?



Risk Characterization

Is substance hazardous and will there be exposure?



Risk Management

Develop procedures to minimize exposures





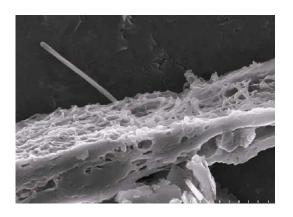




Lab and Field Investigations are Underway



















Health Hazard Research for ultrafine (<100 nm) TiO₂

- Weight of evidence suggests tumor response
 - Results from secondary genotoxic mechanism
 - Related to physical form of inhaled particle
 - Rat tumorigenic data are sufficient and appropriate for making preventive recommendations
- In vivo studies indicate NanoTiO₂ causes:
 - pulmonary inflammation
 - lung tissue damage
- Concern: Existing OELs for larger TiO₂ may not be protective for Nano TiO₂





Health Hazard Research - Carbon Nanotubes

<u>Aspiration of SWCNT resulted in:</u>

- Rapid but transient inflammation and damage
- Granulomas and fibrosis
- Rapid and progressive interstitial fibrosis
- SWCNTs more fibrogenic than an equal mass of ultrafine carbon black or fine quartz

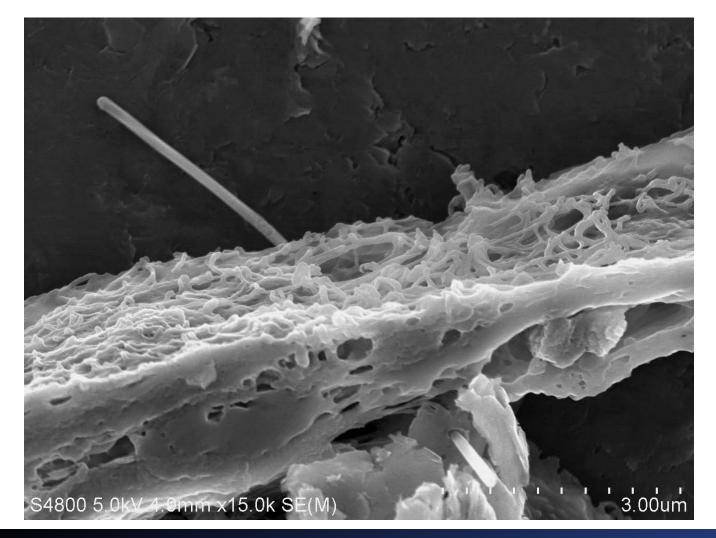
Inhalation of SWCNT and MWCNT

- Similar results using less mass: inflammation and fibrosis
- Evidence of migration of MWCNT to pleura
- Evidence of cell division disruption





MWCNT Penetration of Pleura

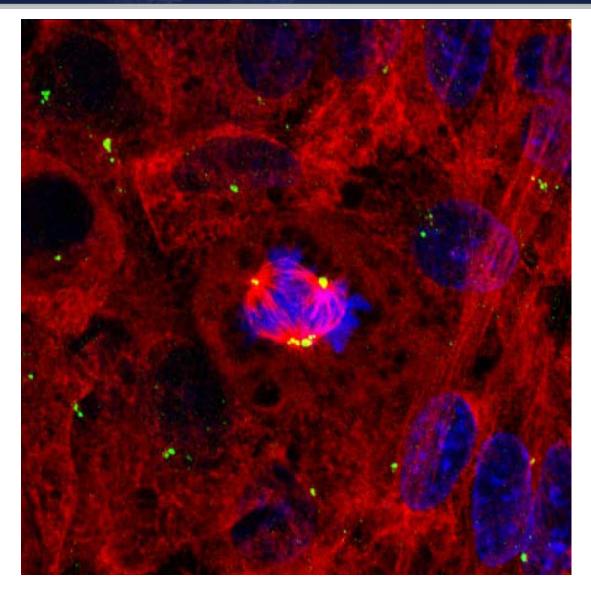












Tripolar mitosis following exposure to .024 µg/cm² SWCNT



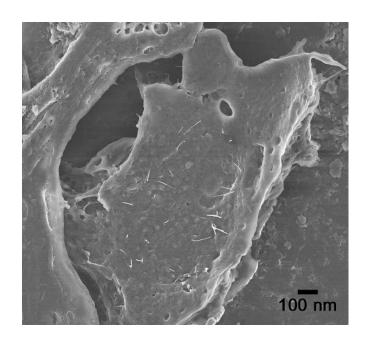






Toxicology Take-Home Message

Exposure limits for the large form of the material may not be protective for the nano size.



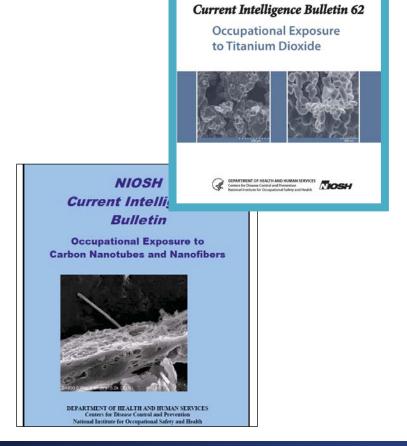






Closing Risk Management Gaps Current Intelligence Bulletins_

- Describe the hazards
- Set exposure limits NIOSH RELs:
 - 300 ug/m³ for Nano TiO₂
 - 2.4 mg/m³ for fine TiO₂
 - 1 ug/m³ for CNT and CNF
- How and where to measure exposures
- Limits of controls
- Research needs



CDC Workplace









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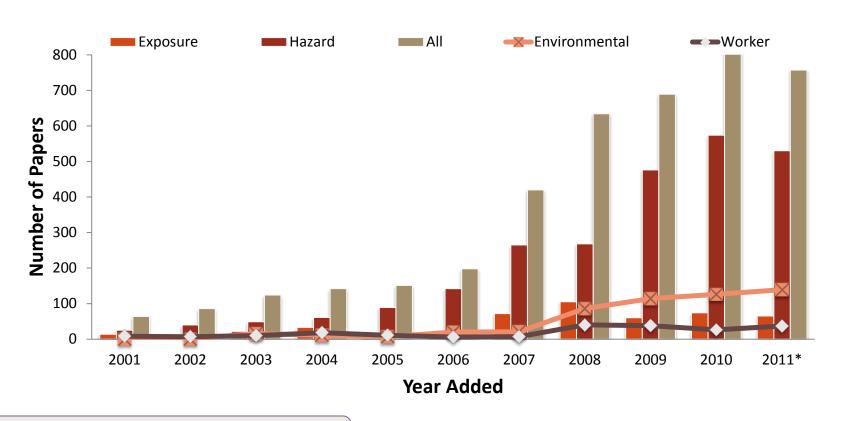






Do we have exposure data to mine?

Peer Reviewed Nano Environment, Health and Safety Journal Articles



http://icon.rice.edu/research.cfm

Not really.





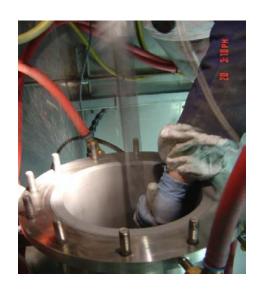
Exploratory Research

Exposure Assessment in the Real World























First Generation Products







Potential worker exposures can occur during the use of many early product applications of nanomaterials.











Exposure and Emission Measurements





Qualitative

Confirmation: e.g. TEM with elemental analysis

Mass concentration



Particle number

Size distribution (count or mass by size)



Surface area















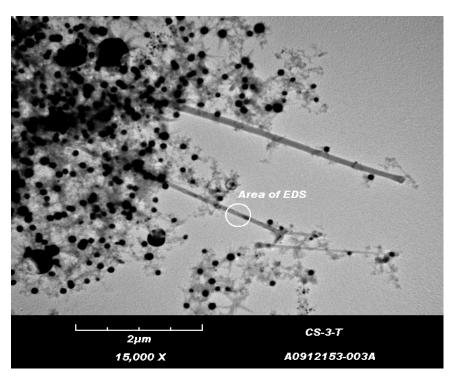




Harvesting SWCNTs from a Carbon Arc Reactor

Task-based PBZ air sample analyzed via TEM w/ EDS



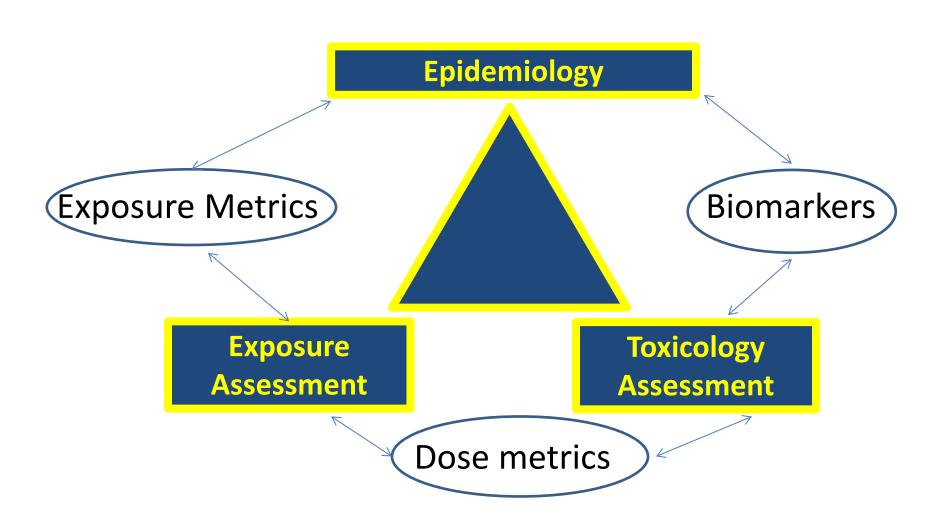








Research is underway to Connect the Key Exposure Assessment Elements



Exposure Data: Conclusions/Challenges

- We have addressed a small piece of the pie
- Exposures do occur in the workplace
- Exposure limits are being developed
- Mass is still the primary metric for exposure
- Direct-reading approaches have a place
- Additional metrics need to be explored: fiber count?
- Confirmatory methods are needed
- Controls can be effective





The Classic Risk Model

Hazard Identification

Is there reason to believe this could be harmful?



Exposure Assessment

Will there be exposure in real-world conditions?

Risk Characterization

Is substance hazardous and will there be exposure?

Risk Management

Develop procedures to minimize exposures









Benefits of a Categorical Approach

- More efficient use of data
- Reduced costs and animal use
- Increased sample size
- Greater robustness of results
- Increased biological plausibility for other materials in same mode of action (MOA) category

[OECD, Env/JM/MONO(2007)28]

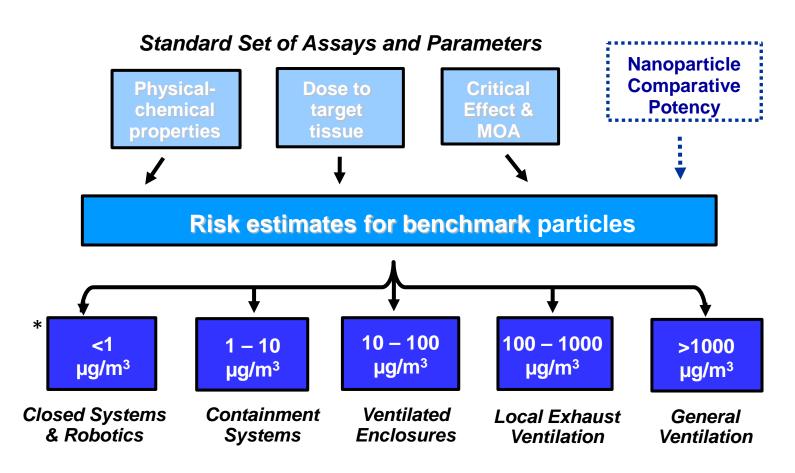
New guidance on methods for grouping chemicals: OECD, ENV/JM/MONO(2014)4







Risk Assessment in Hazard & Control Banding



^{*} Example of exposure control bins developed in pharmaceutical industry; 8-hr TWA concentrations [Naumann et al. 1996; Ader et al. 2005; Zalk & Nelson 2008];







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Is there reason to believe this could be harmful?



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Develop procedures to minimize exposures









Manufacturing Containment











Controls for Laboratory-Scale Work



- Effective controls that factor budget and space limitations are available
- Select controls based on task-based exposure risks







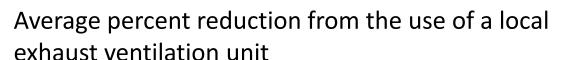






Case study: use of LEV during reactor cleanout





96 +/- 6% based on particle counts

88 +/- 12% based on **mass**



Next version...

Methner, JOEH June 2008









Recommendations

Personal Protective Equipment

- Provide respiratory protection when exposures can't be controlled below the REL
- Provide protective clothing and gloves when there is potential for contact contaminated surfaces (i.e., when technical methods to control exposure are unsuccessful)







Regulatory Agency Activity

- OSHA
 - Use existing regulatory framework
 - Advised to work more with NIOSH
- EPA (TSCA)
 - Pre-Manufacturing Notice actions (consent orders)
 - Significant New Use Rules (TSCA)
 - Pesticide registration (FIFRA)
- FDA
 - Recent guidance for food and cosmetics
- CPSC
 - Nanomaterial position statement









Nanotechnology Guidance Documents



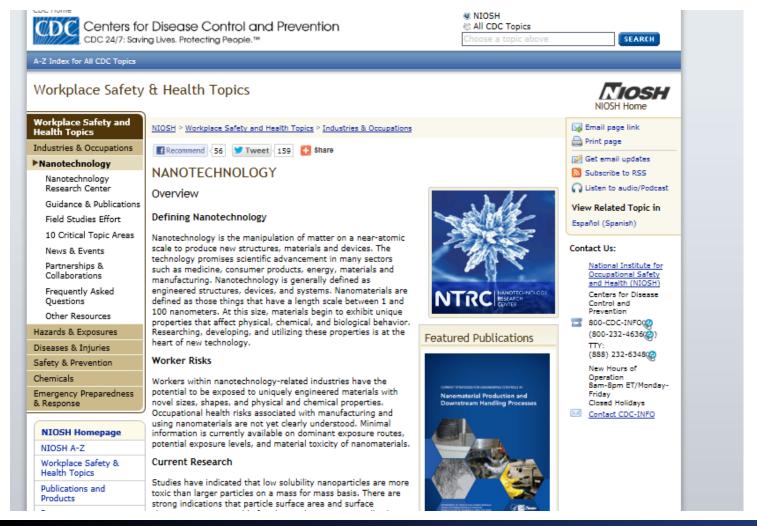






NIOSH Nanotechnology Topic Page

http://www.cdc.gov/niosh/topics/nanotech/







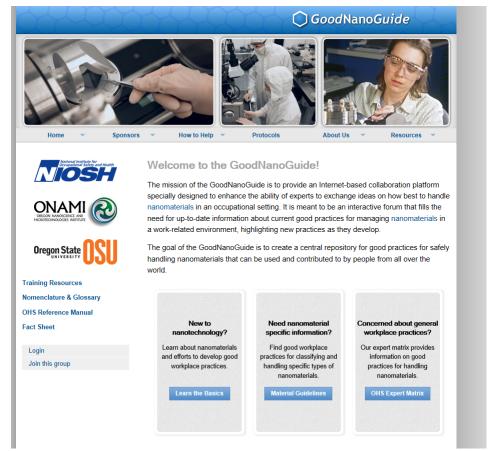




https://nanohub.org/groups/gng



GoodNanoGuide









Communications on Case Reports

NIOSH Science Blog

Safer Healthier Workers

NIOSH > NIOSH Science Blog







Nickel Nanoparticles: A Case of Sensitization Associated with Occupational Exposure

Categories: Nanotechnology

May 28th, 2014 8:17 am ET - Charles L Geraci, PhD; Paul Schulte, PhD; Vladimir Murashov, PhD

In an article published online May 8, 2014 by the American Journal of Industrial Medicine &, researchers W. Shane Journeay, Ph.D., M.D., and Rose H. Goldman, M.D., MPH, report the case of a worker who developed sensitization to nickel when working with nickel nanoparticle powder.

According to the details of the case presented by Journeay and Goldman: "A 26-year-old female chemist formulated polymers and coatings usually using silver ink particles. When she later began working with nickel nanoparticle powder weighed out and handled on a lab bench with no protective measures, she developed throat irritation, nasal congestion, 'post nasal drip,' facial flushing, and new skin reactions to her earrings and belt buckle which were temporally related to working with the nanoparticles."The abstract continues, "Subsequently she was found to have a positive reaction to nickel on the T.R.U.E. patch test, and a normal range FEV1 that increased by 16% post bronchodilator."1

Journeay and Goldman add valuable new scientific evidence to the ongoing base of knowledge about the need for a proactive approach to addressing potential occupational health and safety implications of nanomaterials in the burgeoning global nanotechnology industry. Case studies by alert clinicians are important to NIOSH and its partners in assessing risks posed by occupational exposure to nanomaterials, and in making recommendations for appropriate riskmanagement practices.

The basic association between exposure to nickel and the worker's symptoms is not surprising. An ample body of scientific evidence associates exposure to nickel in traditional forms with risk of respiratory and skin sensitization. The immediate question raised by the case study is this:







Complicating the Task

- Applications research is moving faster that EHS research
- No overt cases of injury or illness reported
- "Nano has gone stealth"
- Reporting and tracking requirements are minimal
- A precautionary approach, though warranted, is difficult to sell







Take Home Message

- Nanotechnology is here to stay
- It will be integrated onto multiple 'sectors'
- There are OS&H issues, and they are real
- The OS&H issues can be managed
- Effective risk management now is good for:
 - Workers and the modern workplace
 - Public trust and societal benefit
 - Business and a competitive advantage







Advanced Manufacturing







Objectives

- Advanced Manufacturing
 - What is 'Advanced Manufacturing'
 - Key drivers
 - Benefits and concerns
 - OS&H issues?
 - Current state of adoption
 - How will it change the workplace?









Defining Advanced Manufacturing

We are moving from the Industrial Age to the Information Age, but we still need to make things.

How we make things is evolving from mechanical processes (traditional manufacturing) to information and technology based processes (advanced manufacturing).







Attributes of Advanced Manufacturing

- Heavy and increasing use of information technology
- Modeling and simulations in manufacturing processes
- Closing the innovation to commercialization gap
- Flexibility to meet customer need
- Sustainable manufacturing (including worker safety)







Trends, Examples?

- Semiconductors
 - Foundation of information technology applications
 - Rapid research to improve performance
 - New materials and structural technology
- Advanced (Nano) Materials
 - Superior performance properties tuned needs
 - Enhanced performance; reduced quantities
 - Computational engineering



More Trends, Examples?

- Additive manufacturing
 - 3D Printing
 - Direct write
- Synthetic Biology
 - Manufacture biological substances from engineered biological systems
 - Biomanufacturing: using biological templates or processes for manufacture of materials systems







The US Landscape

- Advanced Manufacturing Partnership Steering Committee
 - Build public-private partnership environment
- National Network of Manufacturing Innovation (NNMI)
 - Requested \$1 Billion investment matched by private sector
 - Create 15 Manufacturing Innovation centers over the next 5 years, as many as 45 in 10 years









REPORT TO THE PRESIDENT ACCELERATING U.S. ADVANCED MANUFACTURING

Executive Office of the President
President's Council of Advisors on
Science and Technology

October 2014



Reviews significant actions of the Advanced Manufacturing Partnership (AMP)

Recommendations on:

- Enabling innovation in emerging manufacturing technologies;
- Additional investments in innovation
- Securing the talent (worker) pipeline
- Improving business climate for innovative manufacturing firms.

"A broad public-private coalition involving business, labor, academia, government, and the community".









NNMI

America Makes: National Additive Manufacturing Innovation Institute

Digital Manufacturing & Design Innovation Institute

Lightweight & Modern Metals Manufacturing Innovation Institute

Next Generation Power Electronics Manufacturing Innovation Institute

Integrated Photonics Institute for Manufacturing Innovation (IP-IMI)

Institute for Advanced Composites
Manufacturing Innovation (IACMI)







NNMI Highlights

- National Additive Manufacturing Innovation Institute (now known as America Makes)
 - Launched in 2012 in Youngstown, OH
 - A 94-member consortium of business, academia and non-profits
 - Focus on grow of additive, AKA, 3D Printing

A key activity for the Industrial Hygienist because additive manufacturing is happening now!







NNMI Highlights (Cont.)

- Digital Manufacturing & Design Innovation (DMDII) Institute
 - Established February 2014 in Chicago
 - will address the life cycle of digital data interchanged among design, engineering, manufacturing and maintenance systems, and flowing across a networked supply chain

How will the digital interface between the worker and the process impact or benefit OS&H?





NNMI Highlights (Cont.)

- Lightweight & Modern Metals Manufacturing Innovation (LM3I) Institute
 - Established February 2014 in Detroit
 - Transition of advanced lightweight and modern metals manufacturing capabilities and new technologies to the industrial base

Transportation/Aerospace industries are already engaged.







NNMI (Cont.)

- Next Generation Power Electronics National Manufacturing Innovation Institute
 - Established in 2014 in North Carolina
 - Enabling the next generation of energy-efficient, high-power electronic chips and devices by making wide bandgap semiconductor technologies

The semiconductor alternative. Spawning an entire new industry!







NNMI

- Integrated Photonics Institute for Manufacturing Innovation (IP-IMI)
 - Funding opportunity announced in 2014
 - Ari Force major funder
 - Establish a state-of-the-art in the design,
 manufacture, testing, assembly, and packaging of complex photonic integrated circuits

Still too new to evaluate OS&H impact.









NNMI

- Institute for Advanced Composites Manufacturing Innovation (IACMI)
 - Established January 09, 2015, at the University of Tennessee, Knoxville
 - develop lower-cost, higher-speed, and more efficient manufacturing and recycling processes for advanced composites.

Nanocomposites are already poised for high-volume application. This accelerates the process!









Additive Manufacturing: a simple view

Traditional

Billet

Machining

Part

Scrap









Additive Manufacturing

Foil/Powder

AM

Part

Scrap



Additive





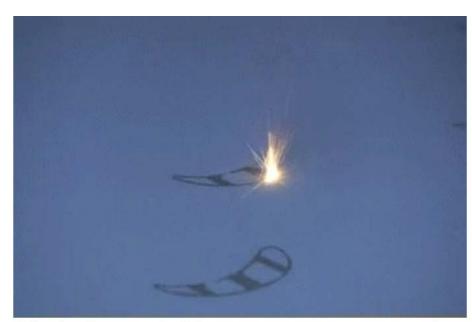




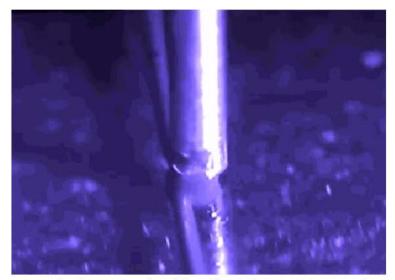




Additive Manufacturing: Now



GE scientists are devising new ways to put sensors in hard-to-reach places through Direct Write technology.



GE Aviation was looking for alloys to 3-D print jet engine parts. They found them in alloys that are used for joint replacements and dental implants.







The Nano-NNMI Link

- Nearly every process uses advanced materials
- Manufacture of a material or a product is the final output
- Skilled workers are needed
- Occupational safety and health approaches will need to mature with the technologies







Special thanks to the NIOSH Nanotechnology Research Center





2010 2012



www.cdc.gov/niosh/topics/nanotech/









Thank you!



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