Practical Safety Guidance for Academic Research Involving Engineered Nanomaterials

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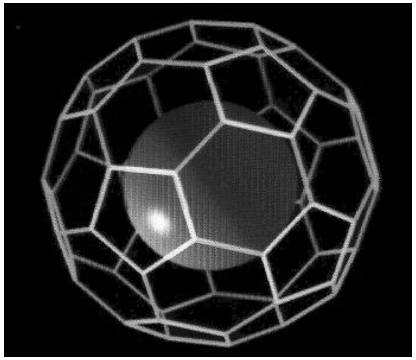
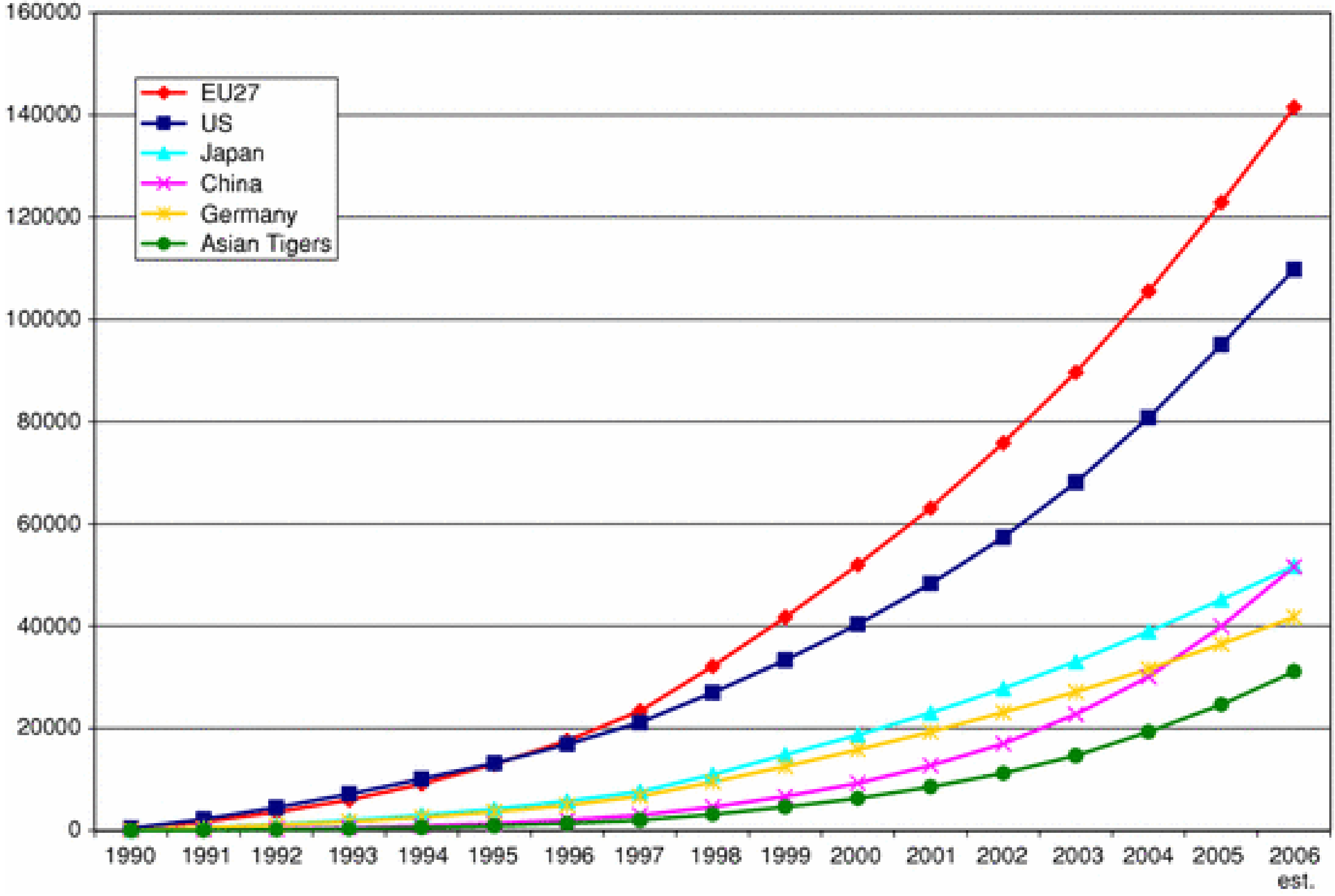


Overview

- Engineered nanomaterials (ENMs) use in academic research
- Risk assessment/risk management approaches in research laboratories
- Is there a need for unique ENM protocol in research environment?
- Practical safety practices and procedures for managing ENM risk in research activities

Cumulative nanotechnology publications by Country/Country Bloc



Yowtie, Shapira, Porter. "Nanotechnology publications and citations by leading countries and blocs " J. of Nanoparticle Research, Jan '08

Use of ENM in the United States

- All 50 states and the District of Columbia have at least one company, university, government lab, or organization working in the field of nanotechnology.
- The top 6 Nano Metros (each with 30 or more entries) are: Boston; San Francisco; San Jose, Calif.; Raleigh; Middlesex-Essex, Mass.; and Oakland, Calif.
- The top 3 sectors for companies working in nanotechnology (each with over 200 entries) are: materials; tools and instruments; and medicine and health.
- **The number of universities and government laboratories working in nanotechnology is substantial, with 182 identified.**

Putting Nanotechnology on the Map, Woodrow Wilson Institute Project on Emerging Nanotechnologies
http://www.nanotechproject.org/news/archive/putting_nanotechnology_on_map/

Academic Research Laboratory Nano-safety Surveys

- A 2006 Workplace survey (of all sectors) indicated that of 6 responding university labs using ENs, 50% had a nano-specific EH&S program (ICON Nanotech Survey, 2006)

- An online survey shows that most researchers do not use suitable personal and laboratory protection equipment when handling nanomaterials that could become airborne. (Balas et al; *Nature Nanotechnology* **5**, 93 - 96 (2010))*
  - ~10% use nano-enabled hoods
  - ~25% do not use any type of general lab protection
  - ~30% use no PPE

*Survey primarily of nano-use laboratories outside the U.S.

January 2009 DTSC Letter Poses Six Questions for "Initial Phase" of Data Call-In for carbon nanotube users

1. **What is the value chain for the company?**
2. **What sampling, detection and measurement methods are you using to monitor (detect and measure) the presence of your chemical in the workplace and the environment?**
3. **What is your knowledge about the current and projected presence of your chemical in the environment that results from manufacturing, distribution, use, and end-of-life disposal?**
4. **What is your knowledge about the safety of your chemical in terms of occupational safety, public health, and the environment?**
5. **What methods are you using to protect workers in the research, development and manufacturing environment?**
6. **When released, does your material constitute a hazardous waste under California Health & Safety Code provisions?**

Stanford Research Community Survey (2009)

- Identified ~130 faculty across 18 departments with an **academic interest** in nanomaterials
- After screening, 33 faculty with **active research** involving nanomaterials
- Subsequent detailed survey with 100% response
- Queried on specific nanomaterials in use and how used

Nanomaterials Survey Items

- CNT
- Fullerenes
- Nanometals
  - Silver
  - Zerovalent iron
  - Gold
  - Other?
- Nanometal oxides
  - Aluminum oxide
  - Silicon oxide
  - Titanium oxide
  - Zinc oxide
  - Cerium oxide
  - Other?
- Other
  - Dendrimers
  - Quantum dots

Survey Results

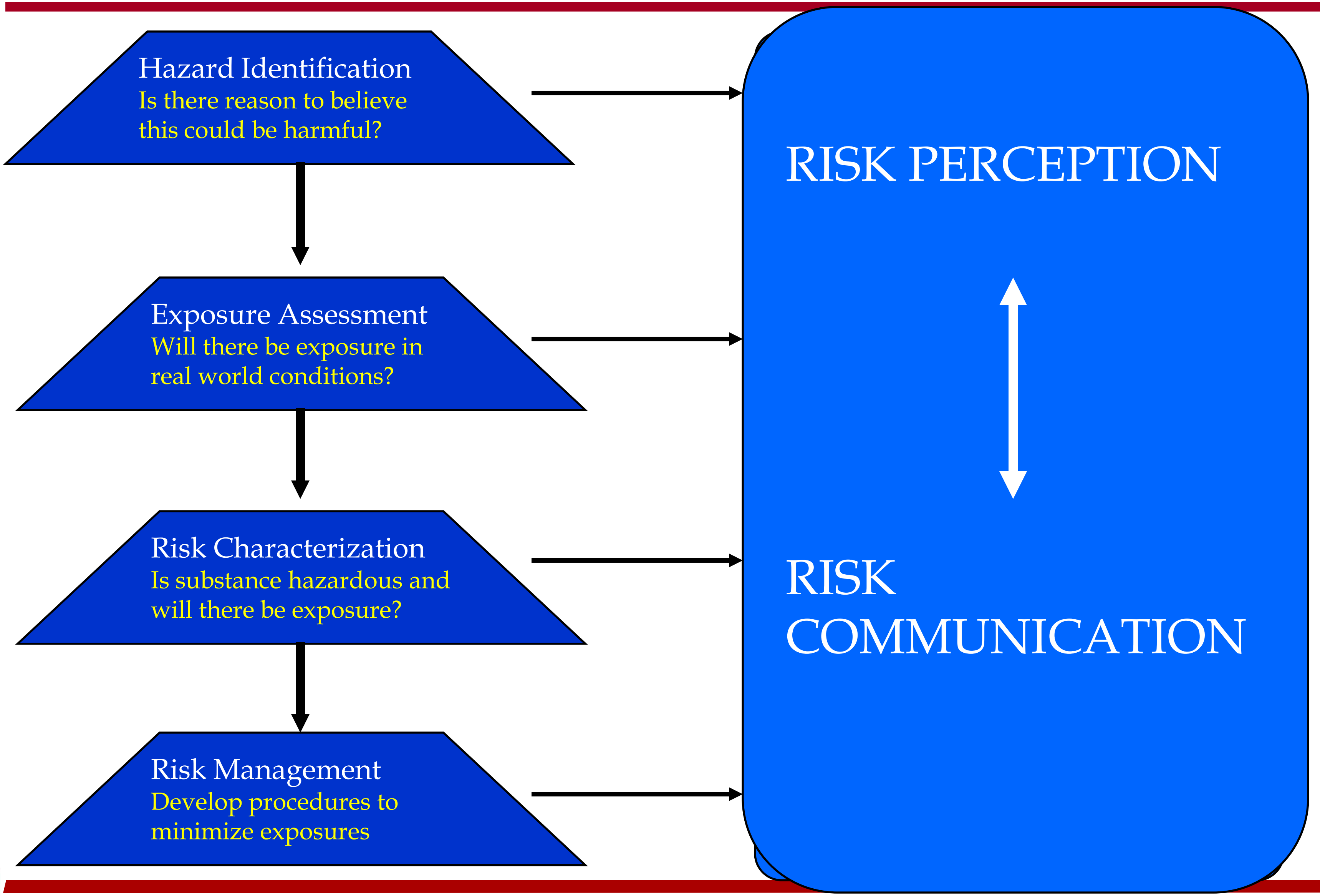
Research Use of ENM at Stanford (33 faculty)

Department	Nanomaterials	Applications
Applied Physics	Carbon Nanotubes	Medical imaging
Radiology	Nanometals	Electronic devices
Biological Sciences	Nanometal oxides	Energy storage devices
Bioengineering	Quantum dots	Fuel production
Chemistry	Dendrimers	Pharmaceutical delivery
Civil & Environmental Engineering		Fundamental physics
Geological and Environmental Sci.		Materials research
Materials Science & Engineering		
Electrical Engineering		
Chemical Engineering		
Mechanical Engineering		

Academic Research Laboratory Environment

- Unique work environment
  - Dynamic, regularly changing types and use of materials
  - Regular turnover of research personnel
  - Often work with materials without full risk characterization (biological agents, radiation, new chemicals)
- OSHA Laboratory Standard
  - Chemical hygiene plan
    - ➢ Safety Operating Procedures (SOPs)
- Integrate health and safety into the research process as much as possible
- Utilize a risk-based approach for safety management

Key Elements of Risk Assessment and Risk Management



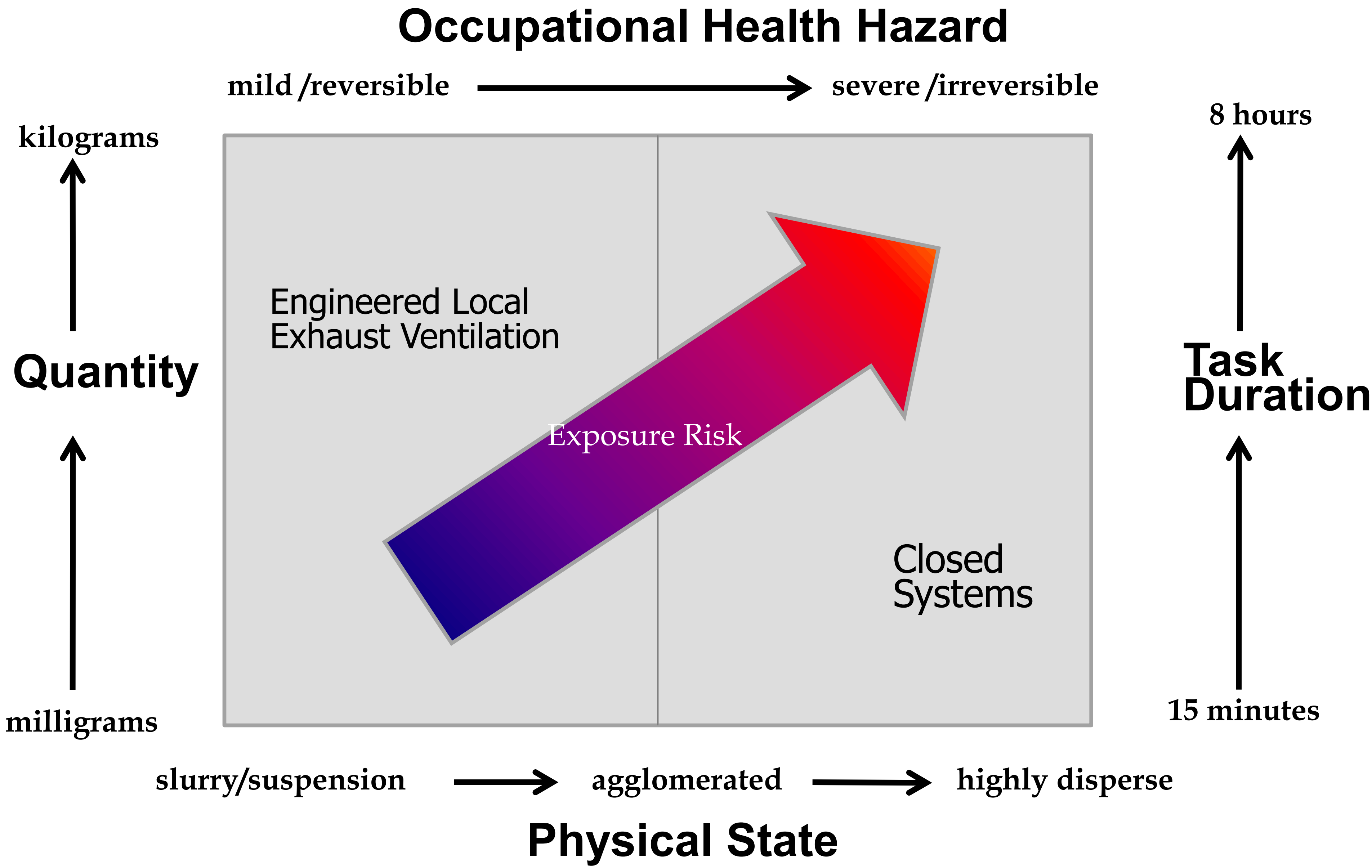
Qualitative Risk Management

- Decision-making without all of the information necessary for quantitative risk assessment
- Draw from:
  - **Established practice**
  - **Analogous materials and situations**
  - **Expert experience and knowledge**
- Develop as:
  - **Good practices for working with engineered nanomaterials**
  - **Use of control banding (risk based) approaches**
  - **New risk management approaches**

Laboratory for Protocol ENM Risk Management

Hazard ID	Exposure Potential	Risk Level	Control Elements to Mitigate Risk
Specific information and knowledge on toxicology and other safety/ health attributes of the specific nanomaterial	Evaluation of the potential for release and uptake of the nanomaterial. Evaluation of the properties of the nanomaterials or procedure that might result in potential for release/ exposure.	Assignment of procedure to a specific determined risk level for subsequent controls. Various schemas ranging from 1-5 levels or bands	Based on specific risk level identified, implement controls that have increasing amount of control characteristics to reduce potential for exposure. Specific controls used are related to each risk level. Ranges from bench top work to total isolation of the nanomaterial from any individual.

Factors Influencing Risk



Controls

- Administrative controls
  - Communication of hazard; posting; labeling
    - Nanoparticle with chemical name
    - Containers through disposal (in California lab waste is by default regulated as hazardous waste)
- Laboratory Engineering controls
  - Lab ventilation - exhaust
    - Chemical fume hoods
    - HEPA filtration
    - Glove boxes/bags
    - Ventilated Weigh stations
- Personal protective equipment
  - Respiratory protection
  - Dermal protection

Laboratory Protocol for ENM Risk Management

Hazard ID	Exposure Potential	Risk Level	Control Elements to Mitigate Risk
	Non-destructive handling of **solid nanoparticle composites** or nanoparticles **permanently bonded to a substrate**	Low (1)	Disposable nitrile or PVC gloves. Do not reuse gloves. Wet cleaning procedures and/or HEPA vacuum for surfaces/equipment
		Medium (2)	
		High (3)	

Laboratory Protocol for ENM Risk Management

Hazard ID	Exposure Potential	Risk Level	Control Elements to Mitigate Risk
Specific Nano material	Working in **liquid media during pouring or mixing**, or where a high degree of **agitation** is involved. Handling **nanostructured powders** -High speed abrading/ grinding nano-composite materials -Maintenance on equipment used to produce nanomaterials **Cleaning of dust collection systems** used to capture nanoparticles	Medium (2)	Conduct task within a fume hood or fully enclosed system (e.g., glovebag/glovebox) Disposable gloves appropriate for the solvent in which the particles are suspended. Do not reuse gloves. Safety eyewear (+ face shield if splash potential exists) Wet cleaning procedures for surfaces/ equipment

Laboratory Protocol for ENM Risk Management

Hazard ID	Exposure Potential	Risk Level	Control Elements to Mitigate Risk
Specific Nano material	Generating nanoparticles in the gas phase or in aerosol (spill or liquid) Manipulation of nanoparticles in gas stream	High (3)	Work in enclosed systems only (e.g., enclosed chamber, glovebox/glovebag)

Multipurpose laboratory example with a range of controls

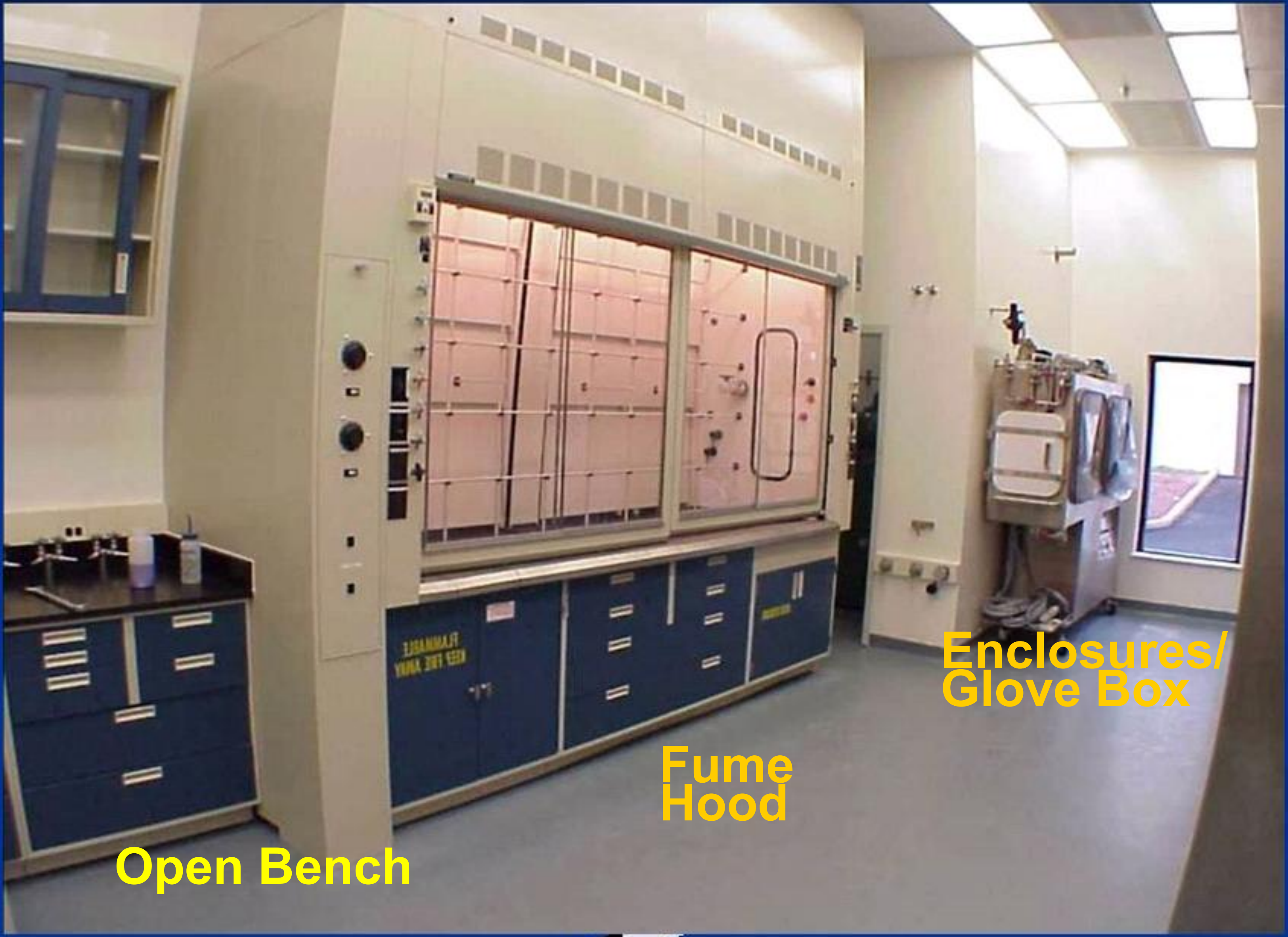


Photo courtesy of NIOSH

Nanomaterials Research Guide:

Safety Practices in the Laboratory

- **What are Nanomaterials?**
- **Current Occupational Health and Safety Concerns**
- **Guidelines for Working with Nanomaterials**
- ***Quick Guide:* Exposure Risks and Control Measures for Common Laboratory Operations Involving Nanomaterials**
- **Spill Response**
- **Disposal**
- **Additional Information and References**
- **Standard Operating Procedure (SOP) Template for Work with Nanomaterials**

http://www.stanford.edu/dept/EHS/prod/researchlab/IH/nano/

Chemical Hygiene Plan

Nanomaterials Use in the Laboratory:

Safety Operating Procedure (SOP) Template

1. Demographic information (who, where)
2. Process or experiment overview (what, how)
3. Risk assessment level
4. Controls
   a) Engineering/ventilation controls
   b) PPE
   c) Emergency safety equipment
5. Step by step operating procedure
6. Decontamination
7. Spill and accident procedures
8. Waste disposal
9. Training requirements
   a) General
   b) Lab specific
10. Required approvals

Engineered Nanomaterials and Laboratory Animal Research

- Scientists
  - ➢Research protocol submittal and review process
  - ➢Activities with direct handling of animals/tissue (dosing, cage management, necropsy, etc.)
- Animal husbandry and personnel
  - ➢ESH related issues in animal research facility
  - ➢Controls and practices for ESH issues, including ENM
- Waste management
- Lab Animal Occupational Health Program

Emerging issues with ENM in research animals

- Existing health/safety research of this area – limited
- Focused evaluation to minimize allergy and asthma related exposures
- Possible use of dander exposure as surrogate for evaluation of controls in place for all aerosols, including ENM

Perception and Regulations

- Lack of sufficient risk information
- Technology has outpaced risk characterization and government regulation
- Organizations develop own principles, practices and procedures
- DTSC – NIOSH – Cal. Universities Project
  - Develop Practical Safety Guidelines for Academic Research Involving Nanomaterials

Guidelines for California Academic Research Using Nano: Working Group Representation

First Name	Last Name	Representing
Khadeeja	Abdullah	UCLA
Jane	Bartlett	University of Southern California
Jay	Brakensiek	Claremont Univ. Consortium
Guy	DeRose	California Institute of Technology
Mary	Dougherty	Stanford University
Chuck	Geraci	NIOSH
Larry	Gibbs	Stanford University (Chair)
Hilary	Godwin	UCLA
Ryan	Kinsella	Cal EPA - DTSC
Rebecca	Lally	UC Irvine
Michelle	Lee	University of Southern California
Frank	Parr	Cal EPA - DTSC
Hamid	Saebfar	Cal EPA - DTSC
Caz	Scislowicz	California Institute of Technology
Larry	Wong	UC Office of the President
Jeff	Wong	Cal EPA - DTSC
Russ	Vernon*	UC Riverside

Working Group Objective

- Develop Practical and Safe Use Guidelines for Academic Research with Nanomaterials for California Universities and Colleges
  - **Phase 1: California college and university health and safety representatives identify and review existing pertinent nanosafety information and develop set of draft guidelines**
  - **Phase 2: Evaluate and assess the effectiveness of the draft guidelines and identify field assessment techniques for academic research**
  - **Phase 3: Incorporate the results of Phase 2 into Finalization of Guidelines**

Phase 1 Activities and Deliverables

- **Review existing data on academic research safety and health involving work with nanomaterials**
- **Identify academic research environments in which nanomaterials are used**
- **Identify nanomaterials disposition from academic research activities**
- **Identify existing knowledge on nanomaterial exposure assessment in academic research**
- **Draft practical guidelines for the safe use and disposition of nanomaterials in academic research environments**

Phase 2 Activities and Deliverables

- **With support of NIOSH and DTSC conduct exposure evaluation of procedures using draft guidelines and controls in academic research environment**
- **Identify possible field methods for exposure assessment for nanomaterials in academic research**
- **Report(s) on evaluation results of propose draft guidelines effectiveness in academic research**
- **Identify nanomaterial exposure assessment knowledge gaps in academic research environment**

Phase 3 Activities and Deliverables

- **Using results of Phase 2 assessment, revise prior draft recommendations as appropriate and finalize Guidelines document.**
- **Identify knowledge and information gaps involving risk assessment and risk management of academic research involving nanomaterials**
- **Plan to post information and guidelines on Good Nano Guide**
- **Plan to present on Working Group process, final guidelines and continuing knowledge gaps at CSHEMA 2011**

Nanotechnology Regulation: Key Regulatory Governance Principles

1. Regulatory response should be coordinated
2. Regulatory approaches should be flexible and adaptive
3. Design information gathering initiatives with endpoint in mind
4. Lifecycle approach to risk management
5. Balance and proportionality between costs and benefits of regulating
6. Clarify accountability and ensure transparency in regulatory system

J Pelley and M Saner, International Approaches to the Regulatory Governance of Nanotechnology, 2009

Summary

- Nanodevelopment is here to stay – need is to ensure safe development, management and end-of-life management
- Working in laboratories with unique and potentially hazardous substances is not a new phenomenon
- Follow prudent practices and procedures that are risk-knowledge based
- Safe Science is Good Science!